THE CONTESTED FUTURES OF BIOBANKS AND INTELLECTUAL PROPERTY

Edward S. Dove* y Yann Joly**
McGill University, Montréal

Summary: 1. Introduction. 2. Intellectual Property Discourse. A) Particular Aspects Of Intellectual Property In Biobanks. B) The Master Narrative Of Intellectual Property. C) Gene Patents And The Power Of Innovation Rhetoric. 3. Biobank Discourse And Challenges To And From Intellectual Property Discourses. A) Public Engagement And Embracing The Social And Political. B) The Uncertain Legal Nature Of Genetic Sequence Databases. C) Open Data Sharing. 4. What Next For Biobanks And Intellectual Property? A) Reframing Intellectual Property. B) A Solidarity-Driven Human Rights Perspective. C) New Policy-Making Logics. 5. Conclusion. 6. Acknowledgements. Bibliographical note.

1. INTRODUCTION

Since the completion of the sequence of the human genome in 2003, science has moved to studying the genetic architecture of complex diseases through genome and genome-phenomena datasets. In the past decade, advances in genomics research and systems and network biology, coupled with increased targeted funding, lower cost high-throughput technologies, next-generation sequencing and nano-chips, and information technology and bioinformatics, have cumulatively led to significant growth of database consortia and biobanks at the global level. While there is an open-end typology in the rich tapestry of biobanks (for example, biobanks can differ on population types, purpose, nature and size of the biological samples and data included, etc.), many stand at the intersection of multiple issues such as medicine and science, markets and public health (Rial-Sebbag and Cambon-Thomsen, 2012). This article focuses on large-scale, longitudinal, publicly funded, population-based biobanks[1].

Because gene-environment and gene-social interactions are complex and large amounts of

* **Edward S. Dove** is a Research Assistant at the Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine, Québec. He holds a B.A. (Political Science) and civil and common law degrees (B.C.L. and LL.B.) from McGill University.

** **Yann Joly**, Ph.D. (DCL), is a Lawyer and an Assistant Professor at the Faculty of Medicine, Department of Human Genetics at McGill University, as well as a research fellow from the Fonds de recherche du Québec-Santé (FRQ-S) and a researcher at the Centre of Genomics and Policy. He holds a LL.B. and an LL.M from the Université de Montréal, Quebec, and a D.C.L. from McGill University.

data and samples are necessary to prove causal relationships, biobanks help enable robust, large-scale genomic analysis and the validation of promising findings via large cohorts. Biobanks also facilitate continuous collections of data over extended time periods, which maximize the value of existing resources and allow researchers to better explore medical conditions, as well as epidemiological and public health issues. Numerous studies have demonstrated the usefulness of biobanking in researching gene-social/environment interactions and subpopulation susceptibility to diseases. Collectively, large international database consortia and biobanks contribute to a core infrastructure in the bioeconomy for translational research (e.g. target identification/validation) and personalized medicine.

Individual biobanks are now pooling data in greater detail between population resources to investigate not only rare diseases, but also common complex diseases. The attendant need for data sharing, interoperability, and openness has led a growing number of funding organizations to require that funded projects swiftly release genomic data in openly accessible repositories. Data sharing, interoperability, and openness are components, along with the collection and transfer of bodily materials, that comprise the current biobanking system and contribute to the scientific endeavour. As with all systems, it operates in an environment that interacts with other actors and systems, including commercial actors and intellectual property-the branch of law dealing with expressed creations of the mind. This latter interaction engenders several fields of inquiry. As well, the bodily component of biobanking engenders new ways of thinking about intellectual property's logic and embeds it in an explicitly ethicized environment.

This article sketches in an impressionistic and conceptual fashion the ways in which traditional intellectual property discourse (IPD) is challenging, and being challenged by, a world that is increasingly marked by the merger of biology, information and technology, as well as the rise of large-scale, transnational biobanks. At the risk of presenting a simplistic binary —though we endeavour to temper it with sufficient nuance and consider it a useful heuristic device— Part 2 introduces the traditional, "closed world" IPD (focusing on patent law) as is typified in developed countries and regions (e.g. the United States, Australia, Japan, European Union). This discourse is then contrasted in Part 3 with emerging "open world" biobank discourse (BD), which is multi-layered and overtly social and political. While neither denying the many significant benefits of intellectual property, nor subscribing to a particular anticipated future(s) and cognizant of the pitfalls of doing so, we will nevertheless discuss several particular aspects of biobanks that are challenging current IPD, namely 1) the vital role of biobank stakeholders (citizens, governments, regulators, researchers, etc.) in governance policy and its associated broader aspects of societal and political decision-making; 2) the uncertain legal nature of genetic sequence databases; and 3) open data sharing. The article then explores how this discourse chasm could cause intellectual property law to recalibrate in order to reflect emerging technologies and democratically engaged practices. The article concludes in Part 4 with the authors envisioning what some of these changes could entail-and how such changes should be welcomed as they will simultaneously improve biobanks and intellectual property law.

2. INTELLECTUAL PROPERTY DISCOURSE

A) PARTICULAR ASPECTS OF INTELLECTUAL PROPERTY IN BIOBANKS

Despite efforts to simplify the process of securing intellectual property rights (IPRs) (e.g. international treaties, centralized patent offices), such rights are still created by national laws and apply only in the countries that grant them. In IPD, IPRs are portrayed as tools to control how knowledge (or more specifically,

an intangible good of a creative kind) will be used. As a property right, it gives the holder of this right the ability to control other people's interaction with the subject matter of that right.

Though the theme of this article is theoretical, it is useful to understand how intellectual property plays a practical role in biobanks. Table 1 outlines the relationship between intellectual property and biobanks; it does not query whether any IPRs in biobanks will be financially beneficial, as is discussed elsewhere (Pathmasiri et al., 2011). This article does not discuss the role of material property rights in biological samples, which, in their natural state, are generally not subject to intellectual property rights since no inventive or creative input is added. Though tangentially related and an extremely important and contentious topic, material property rights in samples are beyond the scope of this article and discussed elsewhere in the literature (Dove, 2011).

Table 1: Examples of possible intellectual property components contained within biobanks

Intellectual Property Right	Components
Copyright	• Software for interviews with participants, health questionnaires, security set-up, and bioinformatic-related software • Structure of genetic sequence databases(s) • Copyright on publication materials arising from biobank research
Trademark	• Biobank name and logo
Patent	• Gene patents • Novel sequencing method or innovative equipment for sample storage • New drug, repositioned drug, diagnostic tool derived from access to biobank's data and samples.

B) THE MASTER NARRATIVE OF INTELLECTUAL PROPERTY

IPRs, and how they are characterized and structured in law, are based on certain norms that society, at least historically, has deemed the "master narrative" (Lyotard, 1984). In other words, when we ask, for example, "What constitutes a patentable invention?", we assume certain legal, socio-economic and political frameworks that make this standard "performative" language (Butler, 1997), such as a political economy based on capitalism and individual property rights. What emerges is a *discourse* (a comprehensive, historically informed term by which we mean all forms of speech, writing, signs, and the ways in which communication is intertwined and serves as an essential aspect of relations of power) (Foucault, 1972) that steers a set point of view of a set of actions (or non-action). In intellectual property, what ties these different rights together is the underlying notion that innovation is a social, *a priori* good and inventors should be rewarded as heroes, while free riders should be chastised as "pirates" and "parasites". In this discourse (seen, for instance, in article 7 of the TRIPS Agreement), limited property rights are the proper function of law and society is the ultimate beneficiary of these limited property rights (Hilgartner, 2009). Largely a Western conceit, it emphasizes individuals and individual rights, and big business and innovation as the path to self-fulfilment and social advance (Vaver, 1997). While historically intellectual property may have advocated a role for the social good, this has all but eroded today.

Moreover, intellectual property operates in a rather "closed world", symbolized by a Chinese box-like framework of national laws and regulations, international treaties or agreements, and bilateral or multilateral agreements. The common denominator in this closed world —or "epistemic community" (Haas, 1992)— is that lawyers (including patent agents and judges) and regulators (including patent examiners and civil servants) act as the two main

(and perhaps only) necessary groups to make innovation and intellectual property properly function; they are, according to Professor Susan K. Sell, "socialized to promote the protection of IP, and uphold the ideology of private property rights" (Sell, 2003: 99). The relationship between inventor and users or consumers of the innovation are separated by multiple but clearly delineated expert intermediaries, including lawyers, regulators, and marketers.

Lawyers and regulators dominate the discourse and are considered experts who are bestowed authority to speak and act on matters relating to the field through autonomous processes of legal reasoning and policy drafting. Consequently, there is little if any *communication* between the epistemic community and citizens. Citizens are *impacted* by the domain's laws and policies, but facing an "expertise barrier" (Parthasarathy, 2010) that is as much agent-driven as structural, they wield negligible power in the decision-making processes behind them. This narrow but powerful "closed world" frame, whereby innovation is trumpeted as the ultimate goal and *sine qua non* metric of success, brackets out contentious and latent legal, political, and ethical issues. This is well documented in the field of genetics patents, which is particularly germane for biobanks.

C) GENE PATENTS AND THE POWER OF INNOVATION RHETORIC

Though increasingly challenged in legal fora (sometimes with success), patent offices around the world grant patents for DNA sequences and entire genes in their non-natural state, provided they fulfil the standard patent criteria (i.e. they are new, have industrial application, and have an inventive step). Yet, there has been sustained criticism of gene patents. Professor James Boyle maintains that there are many arguments against gene patents (e.g. religion, "common heritage of humanity", creeping commodification of nature, ownership of DNA by people whose bodies contain them, etc.), but most are dismissed by intellectual property scholars as not comprising legitimate discourse (Boyle, 2003). Only innovation-centred arguments concerning whether gene patents are patentable subject matter and whether gene patents hinder innovation are accepted as valid material for debate within IPD.

Similarly, Europe's Directive 98/44/EC on the legal protection of biotechnological inventions prohibits gene patents if "their commercial exploitation would be contrary to *ordre public* or morality" (Article 6), yet the determination of *ordre public* or morality is made by judges, lawyers, and regulators, who do not have special expertise or a monopoly on ethical decision-making, yet powerfully shape the terms of the inquiry and the corpus of acceptable evidence. Further, discussions in certain jurisdictions that centre on statutory research exemptions for use of patented inventions —to the extent such exemptions still apply in an age of blurred commercial and non-commercial academic research— fall into the traditional discourse of treating the law as the beginning and end for considering the appropriate scope and use of gene patents[2]. As technologies and biobanks continue to rapidly increase in importance, we must, like Professor Boyle, pose a fundamental question: what does the debate over gene patents teach us about the structure of our legal discipline, about our pattern of inquiry? Or, to take Part 3 of this article as a springboard for exploration: how are biobanks leading to contested futures with intellectual property?

3. BIOBANK DISCOURSE AND CHALLENGES TO AND FROM INTELLECTUAL PROPERTY DISCOURSE

BD embraces technological systems, politics, and open future trajectories. A biobank is fundamentally a *social* and *political* institution with activities (e.g. data collection and transfer, experimental/translational biomedical and epidemiological research) geared towards the

"public interest", that is, interests of present and future society. IPRs, by contrast, are private ends in themselves, not tools to further the public interest. As noted by Knoppers and Chadwick, the inherently shared bodily component of genetic research has engendered "a public and therefore a political examination of personal and social values" (Knoppers and Chadwick, 2005). Biobanking's "open world" normative discourse emphasizes reciprocity, solidarity, and citizenry (Kanellopoulou, 2011), which likely promote more contested positions (deliberate and participatory democracy almost always do), but also more equitable and democratic outcomes. On a practical level, unlike IPD, which is premised on the commercialization of innovations and thus grounds itself in a property model (i.e. intangible goods to be objectified), BD —at least through the eyes of most sample donors and publics— is premised on the principle of non-commercialization of the human body and thus grounds itself in a consent model (i.e. tangible biological samples to be given away). Ploughing deeper, one discovers that the discourses differ on several fundamental levels.

A) PUBLIC ENGAGEMENT AND EMBRACING THE SOCIAL AND POLITICAL

Aside from research outputs that improve knowledge of human health, the success of a biobank is in large part defined by meaningful engagement whereby both participants and the broader community have trust (Critchley et al., 2012). Participants will not give data and samples and the public will not give support if there is not a dialogue (and ideally, a regulatory structure) that fosters transparency and confidence in biobank governance. IPD often emphasizes self-interest (i.e. individual rights and proprietary enclosure around a good), while BD often stresses a participatory approach (i.e. collective goods based on doing the "right thing" regardless of personal or family benefit) (Critchley et al., 2012), though researchers utilizing biobank resources do also consider certain self-interested factors, such reputational reward (Kieff, 2001).

Public participation and engagement is a growing movement in the biosciences. Biobanks establish ongoing relationships with participants and the broader community to foster public trust. Given the long-term nature of biobank research and the need to maintain data and samples for extended periods, biobank participants will not be able to receive all information necessary to have a fully informed picture of who has access to their data and samples, and what commercialization or IPRs may be associated with or derivative from the research undertakings. Though large-scale population-based biobanks are relatively recent, the evidence indicates that there is a strong degree of public trust in the privacy and confidentiality of the use of data (Pullman et al, 2012). However, a single breach of this trust can significantly hinder future biobank research (Critchley et al., 2012).

Biobanks have invested time and energy towards public engagement, albeit in different forms (e.g. community dialogue, small group meetings, focus groups, polls) that depend on cultural, socio-political, financial, and other contexts. Whatever the form of public engagement, it is important to discuss intellectual property aspects of the biobank infrastructure. International norms and guidelines, such as the 2009 OECD *Guidelines on Human Biobanks and Genetic Research Databases* ("OECD Guidelines"), stress that biobank operators should consider which relevant stakeholders, including the general public, should be consulted (Principle 2.D). In particular, a biobank should determine the extent and types of consultations based upon the nature and design of the biobank; the risks involved to participants, their families and identifiable groups; any particular sensitivities related to individuals and groups under study; and the types of research to be conducted (Best Practice 2.5). The greater the breadth of targeted participants and the more extensive the information and data to be collected, the more important it is that broad

consultations be carried out and with diverse groups (Annotations, s. 18).

Even if biobanks are committed to public engagement and fulfil international guidelines in carrying out various consultations, what will happen if many in the community, due to cultural, religious, political, or other significant and meaningful values, express an opposition to IPRs? For instance, Frank Dukepoo, a Hopi Indian and geneticist, has said: "When scientists don't show cultural sensitivity and respect for the beliefs of others —like our absolute opposition to gene patenting— or won't take 'no' for an answer, there is no basis for discussion, and there can be no cooperation" (Brower, 1998: 339). Biobanks seeking to both fulfil their duty to consult and engage the community, as well as foster the means for researchers or pharmaceutical companies to patent disease genes or diagnostic products, may find themselves in a quagmire. If there is clear community opposition to IPRs and the researchers continue nevertheless with the project, trust will quickly erode and compromise the success of genetic population research (as discussed in Part 4 below with the UmanGenomics failure). And if biobanks encourage populations to help set research goals and to view themselves as research *collaborators*, how will these populations respond to IPD, which largely disregards broader governance and engagement issues?

B) THE UNCERTAIN LEGAL NATURE OF GENETIC SEQUENCE DATABASES

Biobanks increasingly rely on online databases to enable scientific research. These databases contain genetic sequence information and also perhaps phenotypic information on numerous individuals. The data explosion in the last several years has led to renewed questions as to databases' status as a legally protected entity. While the issue of open access and data sharing is discussed in the following section, it is important to note here that some biobanks assert proprietary rights over their databases by relying on copyright (especially in jurisdictions outside of the European Union), contracts, unfair competition laws, and/or *sui generis* database protection in the European Union that prevent others from extracting significant portions of the database without consent.

The *sui generis* database protection afforded by the European Database Directive (Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases) presumably covers genetic sequence databases, as the only preconditions for a database to be protected are that it 1) be a systematic collection of independent elements accessible in an individual manner, and 2) necessitated a substantial investment (by way of money, time, effort, technical equipment or human resources) in obtaining, verifying or presenting the content of the database judged qualitatively and/or quantitatively (Gervais, 2007). Moreover, the *sui generis* right may cover not only genetic sequence databases, but also collections of *physical material* (i.e. genetic samples), as "database" is defined broadly to include "other material" apart from works and data (Cornish et al., 2010). Thus, this powerful right may be extended to cover the essential components of a biobank —data and samples (provided they are in a "database")— thereby privatizing the (public) biobank domain even more strictly than envisioned by the drafters of the Directive. However, since biological data can derive from different sources (e.g. from other databases or from sequencing projects), it is an open question whether data in the database has been "obtained", as per the *sui generis* right found in Article 7 of the Directive, and thus receiving legal protection, or database creators invest only in "creating" the contained data, and thus, not counting towards a "substantial investment", do not receive legal protection (Oliva and Carrales, 2011).

Another particularly troubling issue with these *sui generis* rights is that, assuming the European Database Directive does apply to genetic sequence databases, their protection could be extended beyond the 15-year limit

stated in the Directive since the term of protection restarts when substantial additions are made to the database [art. 10(3)], something that occurs regularly in biobanks (Madhavan, 2006). This, along with the uncertainty of the legal protection of genetic sequence databases, demonstrates that when the Directive was drafted in the mid-1990s, internationally collaborative techniques like cloud computing and the fast-evolving and data-intensive sciences like genomics and proteomics simply were not envisioned. Professors Cornish and Llewelyn have noted not only that "[v]irtually no consideration was given [during the presentation of the European Directive] to the position of major scientific databases, such as the biobanks and genebanks, which are crucial to progress in genetics" (Cornish and Llewelyn, 2003: 789), but also that "the *sui generis* database right['s] impact on the collection of data of all kinds in scientific research... went virtually unnoticed during the passage of [the Directive]" (Cornish et al., 2010: 945).

Further, the European Database Directive itself has been viewed as the product of skilful lobbying (Gervais, 2007) rather than solid economic evidence, given that the European Commission itself has remarked that the "economic impact of the '*sui generis*' right... is unproven" (European Commission, 2006), symbolizing well the political leverages wielded by the IPD epistemic community that obstruct meaningful democratic and open decision-making. The consequences for the public are profound: the potential for infinite control of data by the "closed world" domain of intellectual property and an impediment towards the interoperability of data at a global level due to differing legal standards of database protection. As noted by intellectual property scholar Mahesh Madhavan (2006: 81):

> The breadth of protection under the database right can force the scientists to pay for access to genomic data leading to a wave of commercial dominance that will breed monopoly. It can create a monopoly market with no benefit sharing of genomic information even in research environments. For this reason, the second-generation database builders will have to reinvent the wheel, i.e. build new databases from scratch, which is not realistic in the bioinformatics discipline.

Other commentators contend that because biobanks are increasingly tightly controlling access to collected data via data access agreements and ethics and peer review, procedural and contractual mechanisms make the added protection provided by various intellectual property regimes somewhat moot (Parthmasiri, 2011) and more importantly, a rather blunt instrument to purportedly protect innovators and encourage innovation.

C) OPEN DATA SHARING

To a significant degree, biobanks operate in an "open world" environment that relies on myriad publics not only for funding support, trust, data and sample donation, and benefit sharing, but also for enabling robust science. That is, contemporary biomedical science relies on research conducted in distributed networks involving teams of communally-oriented multidisciplinary and multi-institutional players (scientists, bioinformaticians, funding agencies, universities, etc.) that downplays (but certainly cannot eliminate) an individualist ethos often present in IPD. *Sharing*, as opposed to exchanging or licensing, of information and resources is the predominant ethos in the "open world" of biobanking.

As recognized by both the scientific and political communities, data sharing is necessary for scientific progress and requires the development of tools to facilitate the harmonization of international disease and database consortia and biobank infrastructures across national boundaries. A recent survey indicates that more than half of the biobanks in Europe engage in regular international data and sample sharing (Zika et al., 2011), reinforcing the Council of Europe's observation of "increasing cross border flow of biological materials of human origin and data" (Council of Europe, 2006).

Releasing data rapidly into the public domain (known invariably as "open access" and

"open science"), subject to certain restrictions such as legal and ethical obligations to research participants on matters like privacy and informed consent, may be viewed as a primary means of providing benefit sharing and promoting broad social benefits (Joly et al., 2012). Yet, such a practice seriously challenges IPD pertaining to upstream rights claims that encourage exclusive, proprietary ring fences around data and samples (Caulfield et al., 2012). Professor Donna Gitter writes that "there is significant need for a data access policy for publicly funded genomic databases that will ensure the data's accessibility while simultaneously protecting against parasitic patenting" (Gitter, 2007: 1491), which is the filing of dubious patent applications on upstream research and research tools that block other users' access to the data.

Open data sharing demonstrates how multiple actors are using technology and models (e.g. science commons, copyleft, BioBrick™ Public Agreement) to democratize access to knowledge. This differs operationally from IPRs like patents, which often impose high transaction and information costs on various sectors of society. Patents allow not only for commonly acknowledged management rights that control decisions about a resource, but also latent managerial dominion over the social relations surrounding it, as witnessed by the patents on the ovarian and breast cancer genes, BRCA1 and BRCA2 (as well as rights to an analysis of the RAD51C gene), issued to the American molecular diagnostic company Myriad Genetics, Inc. Myriad charges individuals up to U.S. $3,000 for use of its BRCA1 or BRCA2 test and thwarts competitors from producing cheaper alternatives. Inevitably, those in lower income brackets who may not have (any) health insurance, belong to a jurisdiction that pays for the test, or have the money to pay for it out of pocket, are excluded —along with doctors— from this advanced diagnostic test. Of course, patent status is but one of many factors that can impact access to diagnostics and therapeutics. Yet, it must be stressed that in general, poorer people also suffer from more health problems and this does not factor into patenting decisions, which manifest almost exclusively from economic determinants.

Thus, the power that a patent holds on something difficult to invent around (Lee, 2009; Huang, 2006; Heller and Eisenberg, 1998), such as a disease gene, arguably constrains[3] people from participating in decision-making and wider negotiations about technology-though Professor Peter Lee argues, within an innovation-centric discourse, that patents encourage "theorizing around" technical problems and promote scientific paradigm shifts (Lee, 2004). Biobanks that stimulate open access and researchers to share in the creation of knowledge confront intellectual property's monopolies of configuration power (influencing how technologies are connected with the social world) and limits on democratic choice. This is not to render a negative indictment of intellectual property *per se*. But, it does give legitimate consideration to the hidden socio-political determinants of intellectual property policies that shape biobanks and publics, and causes us to reflect on the need for a wider analysis when considering the impact that gene patents, *sui generis* database protection privileges, and other forms of property rights can have on biobanks and associated emerging technologies.

4. WHAT NEXT FOR BIOBANKS AND INTELLECTUAL PROPERTY?

If we accept that biobanks and intellectual property will face contested futures, many jurisdictions may no longer accept a status quo system, comprised of complex laws, that views itself predominantly, if not exclusively, as economic and technocratic rather than social and political. It is critical to situate intellectual property in its historical context. Professor Adrian Johns reminds us that, "When we talk about intellectual property, we are necessarily historians for the duration. We have to be,

because the very concept involves notions of origination and authorship that demand excavation of the past and narrative explanation of its relation to the present" (Johns, 2006: 162). As early as 1869, the venerable and non-radical newspaper *The Economist* predicted that "the patent laws will be abolished ere long". The scientist-philosopher Michael Polanyi advocated systemic patent reform in 1944 (Polanyi, 1944), as did economist Edith Penrose in 1951 (Penrose, 1951). The United States government has long recognized that systemic change in that country was needed, but absent a change in discourse and greater political involvement, little would change (Machlup, 1958).

Certain sub-systems within intellectual property have undergone incremental change, such as copyright, but little has changed in others, such as patent law. More critically, however, systemic change has never occurred. Rather, both the post-World War II and the post-Keynesian neo-liberal world order have imposed an internationally harmonized system of standardized law and discourse. Seen in a historical context, because the United States and other industrialized countries, mainly in Europe, wanted to ensure that industrializing countries like Japan would embrace the patent system, large diplomatic efforts went into establishing supranational organizations like the World Intellectual Property Organization (WIPO) to establish basic uniform standards for intellectual property protection and maintain the master narrative. WIPO, in turn, now falls in tune with the neo-liberal approach of the World Trade Organization and TRIPS Agreement. Consequently, the politics of intellectual property is hegemonic, severely under-developed (Boyle, 1997), and isolated from a broader social milieu (May, 2002).

This trajectory is surely being challenged not so much by economic orders (as much of the world now embraces or accepts the neo-liberal order) as social ones, and biobanks are what we consider a prime example of this. Biobanks are becoming increasingly transnational and equitable in character and are working towards closing the life sciences gap between developed and developing communities. Their multidisciplinary and multi-actor approach challenges the traditional conception of what intellectual property deems a "producer" or "innovator". Is it still the researcher who isolates the disease gene and patents it, or can it not be (alone or in concert with) the donors who facilitated the research and discovery process? The juridical concepts of patent pools and co-ownership do not provide clean answers and exclude social and political factors. More broadly, should we even maintain such rhetoric of "producers" and "innovators" or instead, conceptualize a new "open world" discourse that embraces modes of public involvement in intellectual property development and decision-making?

A) REFRAMING INTELLECTUAL PROPERTY

If IPD is to evolve from its current stasis, the extant law undergirding it may need to undergo a profound endogenous, systemic change. Some argue for specific improvements (e.g. more patent pools) over sweeping reforms. Our vision for a synergistic biobank and intellectual property relationship requires more extensive juridical and socio-political alteration. This is not a radical plea for the abolition of intellectual property (on the contrary, we think *some* system of property attribution serves many beneficial purposes). Rather, it is an entreaty that the domain recognizes and embraces its socio-political dimensions and works with —not against— broader human rights in our modern biobanking world. So that biobanks operating in modern liberal democracies (in developed and developing countries) and in a neo-liberal economic order sustain public trust and, ultimately, achieve success (measured by longevity, funding, public support, and scientific output), it is imperative that intellectual property laws and regulations affecting biobanks 1) fulfil principles of fundamental justice (i.e. are clear and well drafted and therefore understood by more than specialized lawyers) to the greatest pos-

sible degree; 2) integrate with one another and other areas of law; 3) focus on local and global diffusion and needs; 4) include all individuals as units of moral concern; and 5) reflect true citizen involvement. Intellectual property law, like all law, should be open to publics who can affect legislation and policies as much as they are affected by it. That is, publics must be rightfully respected as sophisticated negotiators who co-steer the course of the biobanking endeavour, innovation trajectory, and research outputs.

B) A SOLIDARITY-DRIVEN HUMAN RIGHTS PERSPECTIVE

Beyond the internal need for modern intellectual property laws that are collaboratively well drafted, well understood, and transnationally interoperable, we also envision two other exogenous elements of change. First is the inclusion of a modern human rights perspective, as a political claim and juridical right, possibly in the form of future standards, policies, or laws or amendments to existing legislation, that would add an essential layer to intellectual property. It would serve two main purposes. First, it would serve as an operational constraint on the epistemic community, requiring them to consider the human rights impact of IPRs and policies before they are implemented or enforced, thus ensuring greater accountability and a check on power. Second, it would explicitly acknowledge the polychromatic realm of socio-political actors and practices. In addition to maintaining economic benefit as a factor, this perspective would adjoin the primacy of human dignity within a solidarity and community-oriented ethic.

Within the intellectual property and biobanking context, this modern human rights perspective would accommodate broad social and political perspectives and consider biobanks as a global public good, whereby their non-excludability allows everyone to share in and have access to their benefits, thus actively fostering the population dimension of biobanking. Such a perspective "buttresses the view that biobanks should be managed under principles that consider the whole of humanity rather than narrower interests, no matter how seemingly benign" (Meslin and Garba, 2011: 459). This perspective would not treat downstream genomic innovations themselves (e.g. molecularly targeted drugs) as global public goods, but by recognizing the multiplicity of socio-political actors and practices and ensuring that biobanks are treated as a resource for the whole of humanity, it would better ensure that exclusive IPRs on biobanks, research tools, and raw data contained in a biobank are minimized and supplemented with measures to enable equitable access to these upstream goods and healthcare more generally.

This would go a long way to preventing what befell UmanGenomics, a Swedish spin-off biotechnology company that pitched itself as "ethics-grounded" (Hoeyer, 2004; Rose, 2003). Its engagement with a publicly funded, large-scale (68,000 individuals) population-based biobank (Medical Biobank at Umeå University's research hospital) led to its collapse in 2003 because of four main disputes over the allocation of IPRs: 1) the contract between the university and Swedish county from which the samples and data were based (Västerbotten) ignored pre-existing research contracts; 2) UmanGenomics was granted monopoly commercial access to the public resource; 3) the contract ignored the fact that donors did not agree to have their samples used for private profit; and 4) the contract disregarded Sweden's "teacher's exemption" rule that allows academics to own the intellectual property they produce. A solidarity-driven human rights perspective likely would have prevented this outcome from occurring. Either through soft-law nudging or legal enforcement of rights claims by regional human rights bodies or other courts or tribunals, it would have encouraged the consideration of views of academics, donors, and publics as being equal to those of private industry, and worked to enforce norms fixated not on property rights (which IPD does well), but on promoting distributive justice and democratic engagement.

C) NEW POLICY-MAKING LOGICS

These first two visions are firmly situated in the legal realm. To avoid falling into a juridification trap or a blind faith in the saving grace of human rights, supplementary aspects at a global governance level should also be considered. Therefore, a second proposed exogenous element of change is the deployment of what Professor Shobita Parthasarathy terms "new policy-making logics" that engender "more iterative processes that [do] not take for granted the social benefits of innovation" (Parthasarathy, 2010: 362).

In the biobanking and intellectual property systems, an alternative logic, perhaps grafted on to biobank mission statements, would allow for more than an "economic benefit" lens when considering the value of IPRs and innovations. In this sense, IPD would retain an innovation-positive dimension, which we think is necessary and reflective of economic reality. However, it removes it as an unexamined centerpiece by allowing —and encouraging— an ethical and social benefit lens to evaluate, with new kinds of evidence and expertise, whether the application of an IPR would leave biobank participants and the greater public better off, beyond traditional financial metrics. Thus, it would not assume every innovation will necessarily generate social benefits. Instead of a linear logic that assumes gene patents lead to a stronger economy and thus a stronger society, an ethical and social benefit lens built on an evaluation mechanism that elides traditional evidence (novelty, economic utility, etc.) with other interests and values worthy of inclusion (health outcomes, potential for unjust enrichment, barriers to access, etc.), would facilitate inquiry into, for example, whether potential social and ethical harms, such as commodification of the human body and inaccessibility to valuable genetic tests or drugs, militates against the standard innovation-centric IPD. Deploying these new policy-making logics would not only promote a more holistic —and accountable— IPD, it would also bring many more stakeholders to the table as experts in their own fields of health, sociology, politics, technology, and ethics.

5. CONCLUSION

This article has posited that "closed world" IPD, characterized by individual rights, property enclosure, and innovation as an *a priori* social good, is challenging and being challenged by emerging "open world" BD that emphasizes communal rights, reciprocity, solidarity, citizenry, as well biobank-related issues such as genetic sequence databases and open data sharing. While reflexivity encourages us to be aware of our biases and value judgments regarding these fields of study, we have attempted to avoid presenting a simplistic Manichean opposition that dismisses one for the other. We therefore sought neither a universal condemnation of IPD nor a heroic portrayal of BD. The literature regarding open access movements persuasively convinces us that the "binary tenor of current intellectual property debates... obscures other important interests, options, critiques, and claims for justice that are embedded in many new claims for property rights" (Chander and Sunder, 2004: 1334). Our impressionistic sketch, though binary, is meant to make overt these other interests and claims for justice.

As biobanks are planting global roots and becoming increasingly transnational in collaborative data sharing and infrastructure development, the time is ripe to query whether intellectual property's fixation on expert decision-making and private goods is the most conducive path to bridging and co-producing open future trajectories with biobanks that emphasize cross-cultural public engagement, citizen-involved decision-making, and open data sharing. We think that the status quo IPD and the still emerging world of biobanking will lead to contested futures where the effects of the mal-distribution and asymmetry of information, knowledge, and genetic "theragnostics" will become more politically sensitive. We therefore presented visions of a

new kind of IPD. Time will tell whether such a new discourse is accepted and whether it will simultaneously improve biobanks and intellectual property law, but surely the emerging "open world" of socio-ethically and politically engaged biobanking is here to stay.

6. ACKNOWLEDGEMENTS

The authors would like to acknowledge the funding support of the Fonds de recherche du Québec-Santé (FRQ-S).

BIBLIOGRAPHICAL NOTE

Boyle J. (2003) Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us. *Advances in Genetics* 50: 97-122.
Boyle J. (1997) A Politics of Intellectual Property: Environmentalism for the Net? *Duke Law Journal* 47(1): 87-116.
Butler J. (1997) *Excitable Speech: A Politics of the Performative*. New York and London: Routledge.
Caulfied T., Harmon S., Joly Y. (2012) Open Science versus Commercialization: A Modern Research Conflict? *Genome Medicine* 4: 17.
Chander A., Sunder M. (2004) The Romance of the Public Domain. *California Law Review* 92(5): 1331-1373.
Chon M. (2006) Intellectual Property and the Development Divide. *Cardozo Law Review* 27(6): 2821-2914.
Cornish W. R., Llewelyn D., Aplin T. F. (2010) *Intellectual Property: Patents, Copyright, Trade marks and Allied Rights* (7th ed.). London: Sweet & Maxwell.
Cornish W. R., Llewelyn D. (2003) *Intellectual Property: Patents, Copyright, Trade marks and Allied Rights* (5th ed.). London: Sweet & Maxwell.
Council of Europe (2006) Recommendation Rec(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin. Strasbourg: Council of Europe.
Critchley C. R., Nicol D., Otlowski M. F., Stranger M. J. (2012) Predicting Intention to Biobank: A National Survey. *European Journal of Public Health* 22(1): 139-144.
Dove E. S. (2011) The Genetic Privacy Carousel: A Discourse on Proposed Genetic Privacy Bills and the Co-Evolution of Law and Science. *Current Pharmacogenomics and Personalized Medicine* 9(4): 1-6.
European Commission (2006) Evaluation of the 1996 Database Directive Raises Questions. *Single Market News* 2006 40: 19, online: http://ec.europa.eu/internal_market/smn/smn40/docs/database-dir_en.pdf.
Foucault M. (1972) *The Archaeology of Knowledge*. London: Tavistock.
Gervais D. J. (2007) The Protection of Databases. *Chicago-Kent Law Review* 82(3): 1109-1168.
Gitter D. M. (2007) Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases. *Houston Law Review* 43(5): 1475-1521.
Haas P. M. (1992) Introduction: Epistemic Communities and International Policy Co-ordination. *International Organization* 46(1): 1-35.
Heller M. A., Eisenberg RS (1998) Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280: 698-701.
Huang K. G. L. (2006) Innovation in the Life Sciences: The Impact of Intellectual Property Rights on Scientific Knowledge Diffusion, Accumulation and Utilization. PhD thesis, Massachusetts Institute of Technology.
Joly Y., Allen C., Knoppers B. M. (2012) Open Access as Benefit Sharing? The Example of Publicly Funded Large-Scale Genomic Databases. *Journal of Law, Medicine & Ethics* 40(1): 143-146.
Johns A. (2006) Intellectual Property and the Nature of Science. *Cultural Studies* 20(2): 145-164.
Kanellopoulou N. (2011) Reciprocity, Trust, and Public Interest in Research Biobanking: In Search of a Balance. In: Lenk C, Hoppe N, Beier K, Wiesemann C. (eds). *Human Tissue Research: A European Perspective on the Ethical and Legal Challenges*. Oxford: Oxford University Press, pp. 45-53.
Kieff S. F. (2001) Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science-A Response to Rai and Eisenberg. *Northwestern University Law Review* 95(2): 691-705.
Knoppers B. M., Chadwick R. (2005) Human Genetic Research: Emerging Trends in Ethics. *Nature Reviews Genetics* 6(1): 75-79.
Lee P. (2009) Toward a Distributive Commons in Patent Law. *Wisconsin Law Review* 4: 917-1016.
Lee P. (2004) Patents, Paradigm Shifts, and Progress in Biomedical Science. *Yale Law Journal* 114: 659-695.
Luhmann N. (Ziegert K. A., transl.) (Kastner F., Nobles R., Schiff D., Ziegert R., eds.) (2004) *Law as a Social System*. Oxford: Oxford University Press.
Lyotard J. F. (1984) *The Postmodern Condition: A Report on Knowledge*. Manchester: Manchester University Press.

Machlup F. (1958) United States Senate, Subcommittee on Patents, Trademarks and Copyrights: An Economic Review of the Patent System. Study no. 15, 1958.
Madhavan M. (2006) Copyright versus Database Right of Protection in the UK: The Bioinformatics Bone of Contention. *World Intellectual Property* 9(1): 61-90.
May C. (2002) Unacceptable Costs: The Consequences of Making Knowledge Property in a Global Society. *Global Society* 16(2): 123-144.
Murray F., Stern S. (2007) Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis. *Journal of Economic Behavior & Organization* 63(4): 648-687.
Oliva M., Corrales M. (2011) Law Meets Biology: Are our Databases Eligible for Legal Protection? *SCRIPTed* 8(3): 227-228.
Parthasarathy S. (2010) Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains. *Science and Public Policy* 37(5): 355-367.
Pathmasiri S., Deschênes M., Joly Y., et al. (2011) Intellectual Property Rights in Publicly Funded Biobanks: Much Ado About Nothing? *Nature Biotechnology* 29(4): 319-323.
Penrose E. T. (1951) *The Economics of the International Patent System*. Baltimore: Johns Hopkins.
Polanyi M. (1944) Patent Reform. *Review of Economic Studies* 11(2): 61-76.
Pullman D., Etchegary H., Gallagher K., et al. (2012) Personal Privacy, Public Benefits, and Biobanks: A Conjoint Analysis of Policy Priorities and Public Perceptions. *Genetics in Medicine* 14(2): 229-235.
Rial-Sebbag E., Cambon-Thomsen A. (2012) The Emergence of Biobanks in the Legal Landscape: Towards a New Model of Governance. *Journal of Law and Society* 39(1): 113-130.
Rose H. (2003) An Ethical Dilemma. The Rise and Fall of UmanGenomics-the Model Biotech Company? *Nature* 425: 123-124.
Sell S. (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*. New York: Cambridge University Press.
Vaver D. (1997) *Intellectual Property Law: Copyright, Patents, Trade-marks*. Concord, ON: Irwin Law.
Walsh J. P., Arora A., Cohen W. M. (2003) Working Through the Patent Problem. *Science* 299: 1021.
Walsh J. P., Cho C., Cohen W. M. (2005) View from the Bench: Patents and Material Transfers. *Science* 309: 2002-2003.
Williams H. L. (2010) Intellectual Property Rights and Innovation: Evidence from the Human Genome. National Bureau of Economic Research, NBER Working Paper 16213. Online: http://www.nber.org/papers/w16213.
Zika E., Paci D., Braun A., et al. (2011) A European Survey on Biobanks: Trends and Issues. *Public Health Genomics* 14(2): 96-103.

NOTAS

1. A population-based biobank (e.g. UK Biobank) has the following characteristics, based on the Council of Europe criteria (Council of Europe, 2006): (i) the collection has a population basis; (ii) it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects; (iii) it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data, and which may be regularly updated; and (iv) it receives and supplies materials in an organized manner.

2. We concede that this objection could be applied to other types of legal provisions outside of intellectual property. Moreover, despite claims of juridical capture by legal experts, this has not stopped judges from factoring morality issues into their court decisions, including those in intellectual property. Yet moral terminologies (e.g. "good faith", "*ordre public*") themselves are used in law to give a specific juridical meaning: "...morality as such has no legal relevance-neither as a code (good/bad, good/evil), nor in its individual values... The law can accept directly normative premises from morals or from other social sources, but can only do so through an explicit transformation" (Luhmann, 2004: 112).

3. Walsh and colleagues argue, albeit from within traditional IPD, that patents on upstream goods like research tools do not constrain downstream biomedical research (Walsh et al., 2003, 2005). A well-cited study conducted by Murray and Stern found evidence for a modest anti-commons effect, with the effect becoming more pronounced with the number of years elapsed since the date of the patent grant (Murray and Stern, 2007). They "reject the null hypothesis that IPR have no impact on the diffusion of scientific knowledge", but also find that "erecting a (property rights) barrier to the accumulation of knowledge does not eliminate all Open Science use of that knowledge" (Murray and Stern, 2007: 683). Other researchers have found opposite conclusions. Huang finds "direct evidence of the adverse effect of 'patent thickets'... and... the patenting of disease and cancer genes generates differential and significant negative impact

on knowledge dissemination and utilization" (Huang, 2006: 179). Empirical research on Celera's patents on certain human genes during the Human Genome Project leads Williams to conclude that they "had persistent negative effects on subsequent scientific research and product development relative to a counterfactual of Celera genes having always been in the public domain" (Williams, 2010).

Fecha de recepción: 23 de marzo de 2012
Recibido con modificaciones: 14 de abril de 2012
Fecha de aceptación: 26 de abril de 2012