BIOTECHNOLOGY IP & ETHICS

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balance in IP rights management, IAM can ensure that IP rights are utilized and applied in a manner that is just and equitable. It is time to shift the focus from shaping IP rights through legislative change and embrace the potential of IAM.

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THE COMMERCIALIZATION OF GENOMIC ACADEMIC RESEARCH: CONFLICTING INTERESTS?

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I. INTRODUCTION

University research has traditionally been "predicated on the free flow and open sharing of knowledge".[1] This foundation has been widely accepted in university mission statements,[2] as well as in international declarations.[3] However, recent studies suggest that commercialization might threaten the traditional free flow of academic knowledge.[4] The influx of patents, confidentiality clauses and material transfer agreements into academia as a result of the commercialization process is suspected of interfering with both access to research results and access to research materials. This is thought to be especially detrimental in biotechnology where protection over upstream discoveries like DNA and genetic

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1 Bryn Williams-Jones, "Knowledge commons or economic engine — what's a university for?" (2005) 31 J. Med. Ethics 249 at 249.

2 See, *e.g.*, Massachusetts Institute of Technology, "The Institute is committed to generating, disseminating, and preserving knowledge, and to working with others to bring this knowledge to bear on the world's great challenges", online: Massachusetts Institute of Technology <http://web.mit.edu/mission.html>; York University, "The mission of York University is the pursuit, preservation, and dissemination of knowledge", online: York University <http://www.yorku.ca/web/about_yorku/mission/>.

3 See, *e.g.*, UNESCO *Recommendation Concerning the Status of Higher-Education Teaching Personnel* (November 11, 1997), Article 12: "... higher-education teaching personnel should be free to publish the results of research and scholarship in books, journals and databases of their own choice ..."; and Article 29: "Higher-education teaching personnel have a right to carry out research work without any interference, or any suppression, in accordance with their professional responsibility ... ."

4 D. Blumenthal *et al.*, "Data Withholding in Genetics and the Other Life Sciences: Prevalence and Predictors" (2006) 81:2 Academic Medicine 137.

sequences can potentially block downstream research, which in turn may curtail the development of and access to new treatments.[5]

This view, however, is not universal. Other studies have noted that criticism of intellectual property and commercialization in biotechnology stems from a few highly publicized system failures related to diagnostic technology,[6] and is not reflected in the evidence in relation to biotechnological research.[7] For example, one study found that despite a growing number of patents on genes, these patents are of little consequence in academia. This was attributed to the fact that patents are not typically used to restrict access by academic researchers and that researchers are not actively concerned with patents while conducting research.[8]

How has commercialization affected academic research? While evidence certainly shows that academic biotechnological research has not been completely stunted by commercialization, it also shows these changes to the research landscape have not been neutral.[9] To this end, our qualitative study aims to help provide a more informed account of how researchers view the impact of commercialization on academic research. The chapter commences by briefly outlining the evolution of commercialization in academia in both the United States and Canada. Next, it presents a short review of literature concerning the impact of commercialization on research, focusing on the impact of increased secrecy in the academic environment. Finally, it will augment this body of evidence by presenting the experiences of ten biotechnology researchers who participated in our qualitative interview study and highlight areas where further discussion may be useful.

5 Megan Ristau Baca, "Barriers to Innovation: Intellectual Property Transaction Costs in Scientific Collaboration" (2006) Duke L. & Tech. Rev. 0004 at para. 20; Michael Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280:5364 Science 698.

6 See, *e.g.*, Myriad Genetics; see, generally, Brian Goldman, "HER2 Testing: The Patent 'Genee' is Out of the Bottle" (2007) 176:10 CMAJ 1443.

7 For a review of these studies, see Timothy Caulfield *et al.*, "Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies" (2006) 24:9 Nature Biotechnology 1092.

8 John P. Walsh, "View from the Bench: Patents and Material Transfers" (2005) 309:5743 Science 2002 at 2002.

9 Richard Gold *et al.*, "Gene Patents: More Evidence Needed, but Policy Makers Must Act" (2007) 25:4 Nature Biotechnology 338 at 338.

II. THE PUSH FOR COMMERCIALIZATION

Many factors have contributed to the growth in university-owned and managed intellectual property.[10] Most significant is the fact that governments are extremely supportive of the commercialization of university research, as changes over the years have permitted its ownership and promoted further investments by expanding the scope of what can be owned.

In the U.S., the most influential factor towards this development was the *Bayh-Dole Act*[11] in 1980, which, among other things, gave universities the right to obtain intellectual property rights in inventions resulting from publicly funded research. This gave industry a financial incentive to contribute to university research because of the potential of reaping exclusive benefits through licensing and commercialization agreements. Another major factor was the United States Supreme Court's broad interpretation of patentable subject matter, which now includes man-made organisms,[12] human genes[13] and genetically modified non-human animals.[14]

In Canada, while there was no law similar to the *Bayh-Dole Act*, Canadian universities committed themselves to triple their commercialization outcomes by 2010 by way of the 2002 Framework on Federally Funded Research. Similarly, despite the fact that the Canadian Supreme Court has rejected patents for higher life forms,[15] it has endorsed patents on DNA sequences and lower-life forms, like plant hybrids.[16]

As a result of these developments, a new entrepreneurial focus has become apparent in many universities. Today, almost every major research university has a technology transfer office. In 2006, it was reported that the technology transfer workforce in the U.S. had grown to over 1,800. This workforce was responsible for reviewing 15,908

10 For a more thorough analysis, see Yann Joly *et al.*, "Impact of the Commercialization of Biotechnology Research on the Communication of Research Results: North American Perspective" (2007) 8:1 Harv. Health Pol'y Rev. 71.

11 P.L. 96-517 (The Patent and Trademark Act of 1980).

12 *Diamond v. Chakrabarty*, 447 U.S. 303 at 310 (1980).

13 A 2005 study found that 20 per cent of the human genome has been patented, with many genes patented as many as 20 times: Kyle Jenson & Fiona Murray, "Intellectual Property Landscape of the Human Genome" (2005) 310:5746 Science 239.

14 U.S. Patent No. 4,736,866 (1988).

15 *Harvard College v. Canada (Commissioner of Patents)*, [2002] S.C.J. No. 77, 2002 SCC 76 (S.C.C.).

16 *Monsanto Canada Inc. v. Schmeiser*, [2004] S.C.J. No. 29, 2004 SCC 34 (S.C.C.).

invention disclosures and filing 15,908 patent applications.[17] In Canada, a growing technology transfer sector reviewed 1,535 disclosures and filed 687 patent applications.[18] The commercialized focus of universities can also be gauged in the formation of significant and long-lasting research sponsorship agreements with major corporations. For example, in 1998, the University of California at Berkeley and Novartis signed a five-year, $25 million agreement, giving Novartis the first right to license the intellectual property produced by the university in accordance with the proportion of its investment.[19] Another telling indicium of the entrepreneurial focus of universities is the emergence of spin-off companies by university inventors. Since the *Bayh-Dole Act* in 1980, over 5,724 companies were formed by academics in the U.S. alone, with 553 such companies forming in 2006. In Canada, 2006 saw the emergence of 31 new academic start-up companies, which brought the total number of active academic companies to 404.[20]

III. SECRECY IN THE COMMERCIALIZATION PROCESS

Beyond influencing the subjects of university research into the most profitable, and not necessarily the most beneficial or accessible areas,[21] a major consequence of this push for commercialization is that it can create a more closed and secretive scientific environment. As we argued in a

17 Association of University Technology Managers, *FY US Licensing Activity Survey*, 2007, online: Association of University Technology Managers <http://www.autm.net/events/file/AUTM_06_US%20LSS_FNL.pdf>.

18 Association of University Technology Managers, *FY Canadian Licensing Activity Survey*, 2007, online: Association of University Technology Managers <http://www.autm.net/events/File/AUTM_06_LS_Canada_FNL.pdf>.

19 Andrew Lawler, "Berkeley Review Dismisses Critics' Fears" (2003) 299 Science 332.

20 Association of University Technology Managers, *FY US Licensing Activity Survey*, 2007, online: Association of University Technology Managers <http://www.autm.net/events/file/AUTM_06_US%20LSS_FNL.pdf>; Association of University Technology Managers, *FY Canadian Licensing Activity Survey*, 2007, online: Association of University Technology Managers <http://www.autm.net/events/File/AUTM_06_LS_Canada_FNL.pdf>.

21 As Willison & MacLeod have noted, "Effort is placed disproportionately on discoveries that would maximize profits to the inventor, by targeting large, potentially lucrative markets, rather than on discoveries that would maximize benefits to society" (Donald J. Willison & Stuart M. MacLeod, "Patenting of Genetic Material: Are the Benefits to Society Being Realized?" (2002) 167:3 CMAJ 259 at 261). A prime example of this is the extensive money put into pharmaceutical research when the majority of diseases can be significantly reduced by behaviour modifications. Research into these factors attracts a disproportionately smaller amount of research dollars because their results are not excludable, and thus not profitable.

previous article,[22] the method and speed by which the results of research are revealed is affected by the motivation to commercialize in government-funded research, sponsorship agreements, as well as consulting agreements. Current research has identified three consequences of increased secrecy in academia. First, it can raise the transaction costs of research;[23] second, it can delay access to research results as a result of publication and presentation restrictions contained in funding agreements;[24] and finally, it can affect the morale of the scientific community.[25]

1. Raising the Transaction Costs of Research

While recent studies have failed to clearly demonstrate that patents deter researchers from working with protected materials, the proliferation of material transfer agreements ("MTAs") has been shown to likely contribute to increasing the transaction costs of research.[26] MTAs are contracts that accompany the transfer of materials between various institutions. In some situations, they are simple letters sent along with samples outlining the terms of the transfer, while in other situations, they are negotiated formal agreements that must be signed prior to shipment.[27] Pioneered by industry,[28] they can contain a broad range of clauses outlining the obligations of the providing and lending institutions. For example, an MTA might outline acknowledgement requirements for the provider in downstream research, limitations on liability, storage requirements and prohibitions on transferring materials outside the receiving

22 Yann Joly *et al.*, "Impact of the Commercialization of Biotechnology Research on the Communication of Research Results: North American Perspective" (2007) 8:1 Harv. Health Pol'y Rev. 71.

23 See, generally, E.G. Campbell *et al.*, "Data withholding in academic genetics: evidence from a national survey" (2002) 287 JAMA 473; John P. Walsh *et al.*, "Science and Law: View from the Bench: Patents and Material Transfers" (2005) 309:5743 Science 2002.

24 See, generally, D. Blumenthal *et al.*, "Withholding Research Results in Academic Life Science: Evidence from a National Survey" (1997) 277:15 JAMA 1224.

25 See, generally, Margo A. Bagley, "Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place" (2006) 47:1 B.C.L. Rev. 1 at 35; D. Blumenthal *et al.*, "Data Withholding in Genetics and the Other Life Sciences: Prevalence and Predictors" (2006) 81:2 Academic Medicine 137-45.

26 John P. Walsh *et al.*, "Science and Law: View from the Bench: Patents and Material Transfers" (2005) 309:5743 Science 2002.

27 Victor Rodriguez, "Material Transfer Agreements: Open Science vs. Proprietary Claims" (2005) 23:4 Nature Biotechnology 489 at 489.

28 *Ibid.*

institution.[29] Most significantly, these agreements also explain the allocation of intellectual property rights in derivative materials and results.

In theory, MTAs are designed to help researchers delineate the rights and obligations of the institutions that provide and receive material. As mentioned, they are essential in terms of liability indemnification, as without protection, the university and the researcher may be liable for any physical or financial injury resulting from the sample's use.[30] They are also perceived to be important because they clarify ownership of intellectual property rights, which in turn ensures that there is sufficient economic incentive to develop inventions derived from use of the materials.[31] For example, an MTA may require the receiving institution to surrender all intellectual property in results obtained from the materials or it may require them to grant the providing institution royalty rights on any resulting intellectual property through "reach-through" clauses.[32]

In practice, however, MTAs can complicate the research process by making it more difficult for researchers to access the materials they need to carry out their research.[33] Indeed, the MTA process has been criticized by researchers[34] and technology transfer officials[35] alike for unnecessarily delaying access to materials and raising the transaction costs of collaboration. For example, one technology transfer official estimated that 90-95 per cent of research materials that are transferred with MTAs do not actually require them.[36] Indeed, MTAs are often an unnecessary step when, for example, they are demanded by universities even when the "researchers want to share materials without constraints" as well as when they are demanded by industry in situations where the materials are neither "valuable to the company [n]or purchasable by anyone on the open market".[37] Governed by freedom of contract, MTAs can contain a broad range of clauses that take time to negotiate. Time is wasted negotiating

[29] James Henderson, "Counterpoint: MTAs are a Practical Necessity" (2007) 25:7 Nature Biotechnology 722.

[30] *Ibid.* at 723.

[31] *Ibid.*

[32] David C. Mowrey & Arvids A. Ziedonis, "Academic Patents and Materials Transfer Agreements: Substitutes or Complements?" (2007) 32:2 The Journal of Technology Transfer 157 at 160.

[33] Megan Ristau Baca, "Barriers to Innovation: Intellectual Property Transaction Costs in Scientific Collaboration" (2006) Duke L. & Tech. Rev. 0004 at para. 20.

[34] See section IV. Qualitative Study, later in this chapter.

[35] See Katherine Ku, "Point: MTAs are the Bane of our Existence!" (2007) 25:7 Nature Biotechnology 721.

[36] *Ibid.* at 722.

[37] *Ibid.* at 721.

MTAs in universities with adequate resources, technology transfer skill and prestige. In universities where these are lacking, the MTA process can lead to unreasonable delays, the acceptance of unreasonable contract provisions or the altogether abandonment of the research project.

2. Publication and Presentation Delays

Another consequence of the commercialization process is its potential to delay the presentation and publication of research results. Indeed, many research contracts, both publicly and privately funded, include provisions allowing the research sponsor to review and approve all communication of research results. A main reason for these provisions is that in order to retain both patentability and profitability, research results must be excludable.

In order to retain its patentability, research cannot be shared until it is for the most part complete and either a patent or a provisional patent application has been filed. If results are published before proper filing, they can be considered "prior art", which would interfere with their ability to be patented. For this reason, publication and presentation of research results can be delayed to ensure that there is sufficient opportunity to protect potentially proprietary information before it is shared with the scientific community.[38] More generally, and more problematically, the prospect of patenting can compel researchers to work in more closed environments to preserve the value of their research at its early stages. While patenting will eventually lead to public disclosure via publication, such disclosure is delayed throughout the research and patenting process, which can take a substantial amount of time.

Efforts to obtain competitive advantage can lead to longer periods of secrecy, and are thus even more problematic. Sometimes these tactics are overt, such as when results are protected as trade secrets through confidentiality clauses contained in research contracts or material transfer agreements.[39] Other times, these efforts are more covert, such as when the researcher holds back certain details or know-how necessary to recreate the results, even after protections are filed.[40]

[38] Jeremy M. Grushcow, "Measuring Secrecy: A Cost of the Patent System Revealed" (2004) 33 Journal of Legal Studies 59 at 79.

[39] Victor Rodriguez, "Material Transfer Agreements: Open Science vs. Proprietary Claims" (2005) 23:4 Nature Biotechnology 489 at 491.

[40] Yann Joly *et al.*, "Impact of the Commercialization of Biotechnology Research on the Communication of Research Results: North American Perspective" (2007) 8:1 Harv. Health Pol'y Rev. 71 at 79.

3. Morale in the Scientific Community

Finally, this secretive scientific environment could have an effect on the morale of the scientific community. In a 2000 study, it was found that "63% of geneticists surveyed reported that data withholding harmed the quality of their relationships with peers, 45% said it affected their satisfaction with their careers and 28% reported ending a research collaboration because of it".[41] In another study of over 2,100 life scientists, 58 per cent reported that the refusal of a colleague to share information impeded the progress of their research, with 35 per cent reporting an overall decrease in data-sharing over the past ten years.[42] Another recent survey came up with similar results, finding that 44 per cent of academic geneticists reported that they had withheld data, while 50.8 per cent reported that data withholding has negatively affected their research.[43]

Commercialization of university research is meant to improve the technology transfer of cutting-edge academic research. However, as the review above suggests, the current commercialization process may have made it more difficult for academic researchers to access and build upon scientific discoveries, and to openly disseminate their research results. Indeed, the secrecy associated with the commercialization process has a troubling impact on the academic research process and as a result, the progression of science. As Rosenberg explained in 1996:

> Just as a physician has a moral responsibility not to do harm, so does a scientist engaged in medical research. Deliberately withholding information or reagents is a violation of this principle. If secrecy slows progress, then human suffering may be prolonged and unnecessary deaths may occur. Although these harms are not the intention of scientists who withhold data, they are the logical consequences of such secrecy.[44]

For these reasons, many have questioned how academia is approaching its role in the technology transfer process. In our qualitative study presented below, we explore the views of ten genomic researchers concerning how they have been affected by the commercialization process. The purpose was to elicit their personal experiences with commercialization so that we could use this information to begin a much needed discussion concerning the commercialization of academic research in Canada.

[41] Margo A. Bagley, "Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place" (2006) 47:1 B.C.L. Rev. 1 at 35.

[42] Donald J. Willison & Stuart M. MacLeod, "Patenting of Genetic Material: Are the Benefits to Society Being Realized?" (2002) 167:3 CMAJ 259 at 260.

[43] D. Blumenthal *et al.*, "Data Withholding in Genetics and the Other Life Sciences: Prevalence and Predictors" (2006) 81:2 Academic Medicine 137.

[44] S.A. Rosenberg, "Secrecy in Medical Research" (1996) 334 N. Eng. J. Med. 392 at 393.

IV. QUALITATIVE STUDY

1. Methodology

We selected this convenience sample of ten genomic researchers based on four factors: (1) past collaboration; (2) large collaborative project representative of a broad range of genomics disciplines, including functional genomics, bioinformatics and molecular genetics; (3) funded by a Canadian research funding organization with a policy on technology transfer; and (4) the nature of their project, which seeks to identify gene regulators in disease, and which has great downstream potential for the creation of commercially valuable medicines and genetic tests.

The study used qualitative methods involving semi-structured interviews, lasting approximately one hour each. The interviews were recorded and transcribed verbatim. Questions addressed three topics:

(1) commercialization and research, aimed at assessing the researcher's experience with commercialization and gauging their general sentiment about its affects on the biotechnology research community;

(2) policy issues, aimed at uncovering their perspectives on the soundness of the current policies addressing these issues at the academic and regulatory level; and

(3) open source models of collaboration, aimed at situating their level of knowledge about some existing alternatives to commercialization and their perspectives on whether these models could help to foster the development of fundamental genomic research.

Data analysis was based on codes developed to describe the various themes that emerged in the interviews. They are organized under seven headings: (i) General Impact of Commercialization, (ii) Impact of Patenting, (iii) Impact of Material Transfer Agreements, (iv) Delays in Publication, (v) Impact of Commercialization on Obtaining Funding, (vi) Conflicts of Interest Involving Students and (vii) Open Science Alternatives to Commercialization.

Ethics committee approval was obtained from the Comité plurifacultaire d'éthique de la recherche ("CPÉR") of the University of Montreal.

2. Results

(a) General Impact of Commercialization

While all persons interviewed recognized being affected by commercialization, their opinions on its impact on academic science varied substantially. On one end of the spectrum, commercialization was viewed as an aggravating, but necessary, part of the modern research landscape. On the other end, it was viewed as burdensome, misplaced and detrimental to the academic research community.

(i) Opinions about Commercialization

For some, commercialization was not viewed as a major impediment to research. Rather, the difficulty identified was that it creates new bureaucratic demands that take time to learn and understand. The major criticism from researchers of this view concerned the lack of education they received about commercialization and what it meant for them. However, as they became more familiar with the process, they found that it was not as problematic as it first seemed.

> "It is incredibly difficult as somebody raised in academia to face this world where the language is completely different, the intentions are completely different and I know for myself at the beginning, there was this sense that this is not really what we should be doing. But once you have experience and understand why things are there, it's not that difficult ... it's also not that big a price to pay to have the freedom to pursue what you want." (Interview 7)

For other researchers, there was unease about the commercialization process. These researchers commented that funding policies seem to be the same for all research. In that respect, they felt that the expectations of these policies in relation to fundamental research were misguided. In particular, the focus of these policies on profit and self-sustainability, rather than on the rapid dissemination of research results, was seen as being at odds with the fundamental nature of their research.

> "I think they have been overly optimistic about how close we are at finding something of financial value in terms of our research ... they are a little bit out of touch with reality in terms of what is beneficial for Canadian genetics and genomics community." (Interview 2)

> "Not all projects have the same expectations of IP. It seems like we are getting standard policies and trying to fit a whole spectrum of research into a standard shoebox that doesn't work. It makes the default position to protect everything rather than a more realistic exploration of what the reasonable outputs of the research may be." (Interview 6)

These researchers also noted that the increased focus on commercialization has led to stricter oversight of research projects. This was highlighted as problematic because it takes away the flexibility to change research directions as projects evolve. In some accounts, the interviewees noted that the need to stick to defined objectives is counterintuitive to the scientific process.

> "It's a bit like selling your academic freedom for the possibility of being able to do more with more money." (Interview 1)

(ii) Commercialization and Secrecy

Interviewees noted that the level of secrecy required to commercialize research was a significant drawback of the commercialization process.

> "This is the most frustrating part ... before disclosing anything to a third party, I have to disclose to the funding agent so I cannot discuss freely with colleagues to figure out whether there is actually something to collaborate on." (Interview 2)

> "It's the most difficult thing to do because scientists want to talk to each other and being put in a situation where you know you cannot discuss observations is extremely difficult." (Interview 7)

Interestingly, there were researchers who did not feel that secrecy in academia could be attributed to the commercialization process. Rather, these researchers felt that secrecy would always exist because of the need to be recognized for their work. Reputation is important to make a name for oneself in the scientific community and it has important implications on the distribution of funding. For this reason, many researchers safeguard their work until they are ready to publish. In this sense, attributing academic secrecy to commercialization may be somewhat misplaced.

> "Obviously you never want to make your data available before you squeeze the best parts out of it. I don't think this is a commercialization issue here, it is more of a publication thing." (Interview 1)

> "Obviously while I have a work in progress that has not been published or patented, I'm not going to go advertising. There is a minimum of secrecy here because I don't want my competitors to know what I am doing if I am (not) ready to publish. It is academic competition, not commercial competition." (Interview 4)

> "Commercialization is one evil, but people stealing your ideas is another." (Interview 9)

However, a problem which can be directly attributed to commercialization is the secrecy that remains after intellectual property protections are filed and the research is complete.

As explained above,[45] the more lasting secrecy employed to obtain competitive advantage can be very problematic for the progression of research, as it leads scientists to give an incomplete picture of their research after it is complete. For example, a researcher may contribute to this lasting secrecy by waiting until patents are granted to publish results, by leaving out certain details in the publication or presentation or by refraining from actively promoting an advancement or discovery.

> "One patent (I worked on) was a product. So we kept that idea a little closer, not describing it in so much detail, in an attempt to give the company that had licensed it a commercial advantage." (Interview 7)

> "We have a scientific director, when he gives talks, he cannot tell us everything and I find it extremely depressing because I would like if someone gives a scientific presentation and tells us about what he has done, for him to give enough information for me to understand it (and validate it). When I ask, he says 'no, this is my secret.'" (Interview 9)

(b) Impact of Patenting

(i) General Thoughts on Patents

Some respondents objected to the validity of patents on genetic material on a fundamental level. They explained that they are undeterred by genetic patents because they do not believe the subject matter is capable of such protection, nor do they believe that such patents would be upheld against them in the event of a challenge. For example, if a researcher was to develop a drug using a patented genetic association, the "owner" of that association would have a difficult time arguing that a purely theoretical discovery should be enforced to the detriment of the practical application of that association.

> "The type of things we discover, they cannot protect without the data. If we succeed with (figuring out how to prevent a disease or developing a therapeutic agent based on a patented gene association) before the original group (that has protected the gene or association) it would be protectable even with an existing patent on the disease association." (Interview 2)

> "I don't think you can morally patent something that naturally exists. It has never happened in other sciences, I don't know why it is happening with genes. Lets say you isolated a gene, you observed it, you sequenced it, you showed its function ... that is very useful because someone else is using that technique to develop a drug. But it's the drug that should be patented, not the gene. I don't think you can challenge any practical application based on a theoretical patent." (Interview 4)

> "The sequence itself isn't a patentable, copyrightable sort of thing to me." (Interview 6)

> "The way I see it, I am a discoverer, not an inventor and I am not sure I would want to patent these discoveries, just as I wouldn't patent Greenland. But on the other hand, the government lets us do it and the funding agencies like us to do it, so we do it." (Interview 10)

(ii) Personal Motivation

While fostering creativity is the classic justification for providing protection through patents, a more current justification of the patent system is its role in ensuring that new technology is efficiently transferred to the marketplace.[46] Indeed, the accounts of these interviews suggest that justifying the patent system on account of its fostering of creativity may be misplaced, as none of the respondents felt that patents motivated their creativity or desire to perform research in any way. These researchers felt that curiosity and the desire to answer questions was the motivating factor in academic research.

> "I think if I wanted to make money on something, I would have gone into a different field. Most scientists at this level are not poor, but I don't think most of us go into this business to be rich." (Interview 1)

> "It has to be the curiosity. We are scientists. The only way to survive in this system is passion and curiosity because I think if you are motivated by something else, it won't work because there is not a lot of money in the system." (Interview 3)

> "It's the thrill of being creative ... you want to do good research because of your own motivation, you have the urge to answer questions." (Interview 4)

> "The scientists I am working with are scientists. They do it for whatever reasons, but most of the reason is that they like to know, they'd like to become famous and they get a kick out of finding new things." (Interview 8)

> "The most peculiar thing about interfacing academic research with the commercial sector is that people believe that academics are somehow going to be motivated in the same way as people in the commercial sector and there can be no bigger mistake." (Interview 9)

[45] See section III.2. "Publication and Presentation Delays", earlier in this chapter.

[46] Matthew Herder & E. Richard Gold, *Intellectual Property Issues in Biotechnology: Health and Industry* (Paris: OECD, December 2007) at 11, online: OECD <http://www.oecd.org/dataoecd/16/9/40181372.pdf.>.

(iii) Impact of Patents on Academic Research

Patents were not perceived as motivating research, but their presence was not seen as inhibiting research either. Indeed, one researcher commented that nothing would be accomplished in the field of basic genomics if researchers were deterred by the presence of patents.

> "If we would be restrained by the world of patents on genes and genetic associations, we wouldn't do much of anything in the context of this project." (Interview 2)

Despite the fact that there is no clear statutory research exception in Canada's *Patent Act*, many of the researchers attributed their ability to work freely with patented materials to their position as academic researchers. Some were of the view that their work could only add value to the initial patents and thus felt it was in the interest of patent owners to allow them to work freely with patented discoveries.

> "We think we add value if there is an existing patent on it." (Interview 2)

> "If someone has a patent on something, it is in their interest to make it freely available to academic researchers because they can find new things to make the patent more valuable." (Interview 4)

> "If I am doing academic research, I don't worry about who has patented what. I am sure half of what I do infringes someone's patent somewhere. Patents may be a reason not to commercialize, but it is not a reason not to do the research" (Interview 10)

Not all respondents felt patenting was irrelevant to productivity. One respondent commented that the process of patenting and its corresponding effect on the dissemination of research results may have an adverse effect on productivity by decreasing access to good ideas.

> "I am pretty sure that it hinders productivity of the community as a whole by reducing access to good ideas." (Interview 5)

Respondents suggested that a more tempered approach to patenting could be warranted. One researcher suggested that researchers should be responsible for determining when they should take out a patent, while another proposed a more collaborative approach between the researcher and funding body (whether governmental or commercial) to determine the intellectual property protocol based on the realistic expectations of the research.

> "What can be valuable as a patent and what may not be ... a lot of the researchers should make this call rather than obliging them to take a patent on everything." (Interview 4)

(c) Impact of Material Transfer Agreements

(i) The Need for Professional Assistance

While patents were not regarded as a major problem, access to materials was felt as greatly hindering university research. In the context of this particular project, the process has been facilitated by the addition of a project manager and technology transfer specialists. Working closely with the technology transfer office was noted to result in a more realistic approach to the potential commercial value of the research. When scientists, business people and lawyers work together, they can more easily determine what realistically will amount from the research, and thus better determine when negotiating MTAs is worthwhile and when it is a waste of time and effort.

> "I asked for some biological materials and it turned out I had to fill out an MTA form. I had no clue what to do with it so it was very nice having somebody here to walk through it with me. It only took a few days as opposed to the weeks it usually takes with the university." (Interview 1)

> "OTT (Office of Technology Transfer) works in the building now so having someone on site who is knowledgeable and who is practical and who takes a straightforward approach to these things that helps a lot." (Interview 10)

(ii) Perception of MTAs

In the absence of such professionals, the proliferation of MTAs was seen as adding a bureaucratic layer leading to unnecessary delays in the research process.

> "It delays research. The old-fashioned way that scientists would trade materials on a handshake and a good faith promise is gone. When organizations start seeing phrases like IP and all these things in writing, it becomes a lot more complicated. More people get involved and there are a lot more questions being asked." (Interview 6)

> "Certain companies are just happy to collaborate, but most of the time you have an MTA and the more lawyers involved the longer it takes." (Interview 8)

However, it was noted that despite the rigid policies, the funding institutions are less strict in practice and will not allow the MTA process to impede research. It was also noted that with experience, technology transfer specialists have begun to take a more sensible approach about when it is and when it is not worthwhile to protect materials. As mentioned above, the approach is changing from a "protect everything"

mentality and is now more focused on what can reasonably be expected from the research.

> "MTAs are more or less a demand from Genome Quebec ... but if it really hampers your collaboration they are more flexible, they understand that we are an academic project." (Interview 8)

> "In the last couple of years the MTAs have become a lot less restrictive. The process used to take weeks or months because everybody was working on different terms but now I am noticing a lot more often when we send an MTA out, it is almost always returned signed. In the last year particularly, people have been a lot less protective of IP that has little or no value. Things seem to have gotten a lot more sensible." (Interview 10)

A key problem identified in the material transfer process was the use of different and conflicting forms by different institutions. To this end, more uniform policies may be beneficial to facilitate material transfer within academia.

> "The real difficulty is that different institutions have different policies and different types of organizations don't have consistent policies. We thought we had a very simple and straightforward MTA, but it bumped up against the one coming back to us, which was very different and the lawyers on both sides got very uncomfortable. General consistency among academia would be good." (Interview 6)

(iii) Experiences with MTAs

Anecdotal evidence from the interviews indicates that complications over access to materials can delay, reduce the quality of and even prevent the completion of research projects.

> "There were some mice ... that a company does not want to send me ... so my collaborator is going to have to make the mouse again, which is a waste ... it will be the exact same mouse but it won't be covered by the patent because it will be a different lineage of mice." (Interview 4)

> "Where we thought we'd be getting samples from, we ended up not being able to (because of licensing restrictions) so we had to look for secondary sources. The delay was one thing, but probably the overall quality of the project suffered because by definition we couldn't get our first choice of samples that we wanted to match the experimental design and so we had to go to a sort of 'plan B.'" (Interview 6)

Not all of the researchers had solely negative experiences with material transfers. When the process works efficiently, it was noted that these agreements can facilitate sharing within the institution.

> "It used to be if I got materials from somewhere it meant only my lab could have it, but in many cases the MTA allows other researchers in the university to use them so in some cases it makes sharing easier within the university once we signed it." (Interview 10)

(d) Delays in Publication

(i) Pragmatic Solutions to Publication Restrictions

Most research contracts require that the funding body, whether public or private, be given an opportunity to review the manuscripts presenting research results prior to publication. Interestingly, none of the researchers found that this process infused any substantial delay in the dissemination of their research. In response to pre-screening obligations, the pragmatic solution has been to submit results for review as soon as they are available. This enables the sponsors to review and file for any necessary protection during the time it takes for the researchers to put together the manuscript for publication.

> "We usually submit papers for review at an early stage where we are not yet ourselves ready to submit it, but all the necessary details are there to determine whether there is any protectable IP. The timelines we are dealing with would almost never hinder us from getting things published in time." (Interview 2)

> "This isn't really a delay because you use that time to edit and improve the manuscript." (Interview 7)

(ii) Problems Before, Not After

While few problems arise once the agreements are in place, researchers did note that problems can arise in reaching an acceptable publication agreement before the projects begin. It was interesting to note that the reason for lack of problems in this respect was that the projects rarely resulted in results that require protection.

> "Once an agreement is in place, there is never a problem with delays because there is never anything there that requires protection." (Interview 1)

> "You know there is never going to be anything, but they like to take control. Considering that what we are doing is basic research, there was never a problem afterwards, but the contracts will take quite a while to sign (in this case, the delay was about 6 months)." (Interview 8)

(iii) Responsiveness by the Body Imposing Delay

Respondents noted that funding bodies were responsive to their need to publish, give conferences and lecture about their research.

"One time we wanted to present at a meeting, something that Genome Quebec insisted we patent before we put in the public domain, and the patent agent worked over the weekend and had it done within three days, so there were no substantial delays." (Interview 4)

"Their official line is 10 days, but they have been very accommodating." (Interview 8)

(e) *Impact of Commercialization on Obtaining Funding*

(i) *How Are Patents Valued?*

None of the respondents felt that patents were necessary in an academic career, but most felt that they were, to a certain extent, beneficial to an academic career.

"There is always a place where you need to put how many patents you have, licenses and so on (in a grant application) and they are being evaluated so if you don't have anything for that square then you get a zero. We as a scientific community would be rather pleased to see the same kind of square to indicate the number of times your data has been translated to clinical practice." (Interview 3)

"I have a few patents, none of which has generated money, but I put them on my CV and it looks impressive." (Interview 4)

"It is certainly valued to some extent on your CV, which is problematic because all patents look the same and it's hard to evaluate what they are really worth." (Interview 5)

"If you look at the distribution of money you will see that people who are running more commercial type research, they are more successful and there is more money going in whereas if you are doing more idea driven research, its more difficult to survive." (Interview 9)

"Completed patents are considered a publication, so there is an academic benefit to doing these things." (Interview 10)

One researcher indicated that patenting behaviour could play a role in determining who would obtain promotions.

"Generally the people more cognizant of IP policy tend to be people more aware of management issues as a whole and I think it's helpful if you are looking for a promotion." (Interview 10)

While none of the researchers suggested that patents were of major importance to research funding bodies at this point in time, some suggested that they could carry more weight in the future.

"I could see with certain funding agencies like Genome Canada at some point it could become an obstacle for me if I don't start to file patent applications." (Interview 2)

(ii) *How Should Patents Be Valued?*

Respondents were unanimous in their belief that the number of patents obtained by a scientist should not factor into funding decisions, unless the patent happens to be successful and clinically useful.

"I think I tend to be more of the academic school that really doesn't think a patent application is an independent publication. It is usually a duplicate publication of a real result and the value of a real result you see from the level of scientific journal it is published in, how many citations it got and how much visibility it gave you in the scientific field." (Interview 2)

"Having a patent does not tell that you are doing good research, it just tells that you are doing something, that somehow down the road may be applied but you are not sure." (Interview 3)

"It can be important for the one in a thousand scientists who discovers something that makes money. Most scientists don't discover anything that makes a penny." (Interview 4)

"I think that just as you have good and bad publications, you have good IP protection that makes a lot of money that the university looks at more favourably and you have bad patents that don't bring in any money." (Interview 8)

One respondent noted a danger for academic research, and indeed the progression of science in general, if commercialization and commercial goals played a greater role in the granting of funding.

"When too many projects are oriented towards demand, the science becomes very uniform. There are huge projects doing exactly the same thing." (Interview 9)

(f) *Conflicts of Interest: Students and Commercialization*

Interviewees expressed that a major problem stemming from the commercialization of academia is the impact that this process has on students. Because students need to present partial or incomplete research results, commercialization limits the type of research that they can be involved in. When they do become involved in commercial research, it also limits their ability to develop a competitive CV.

"Students in training often present partial data at conferences. This partial information is not mature enough to patent ... so research with commercial goals is not the right type of research to put a student on because the student will be put at risk in the sense that they wouldn't be able to present ... so they won't be able to develop a competitive CV ... . It is probably not good to put students there, especially good students." (Interview 3)

Even more serious conflicts arise when student work is used for commercial purposes without their consent. Interviewees noted that the use of student work for commercial purposes, both overtly and covertly, was a prevalent problem in academia.

> "I have seen situations where student theses were used as patent applications without their knowledge ... where students' exams and projects were used to justify a research program without their knowledge ... . I have seen a number of times, at this university and others, students be told to stop pursuing something because it was going to go to a company and someone with more experience would work on it purely as a commercial enterprise." (Interview 10)

Not all researchers viewed student participation in research as inherently problematic. Despite the additional demands placed on students, some researchers felt that it was possible to collaborate with students and industry in a conflict-free manner.

> "We had a post doc that was funded through the industrial partner and the approach we took was that we were dealing with a McGill post-doc who simply had a different source of funding ... the only difference were the quarterly reports on progress and it was understood that if we made any discoveries that were significant, we wouldn't destroy their future commercial potential by speaking about them before we had submitted them as report of invention." (Interview 7)

(g) Open Science: Alternatives to Commercialization

While respondents described the Canadian genomics community as reasonably open, they nonetheless felt that the goals of commercialization were not particularly suited to the more collaborative culture of academic genomic research. However, they were confident that the trend towards immediate access to research results initiated by the National Institutes of Health ("NIH") in the United States may have a positive impact on future research.

> "I think the shift to open science is clear and I think it is driven by the new NIH policy that genome association study results have to be published immediately. I think that these policies will change a lot of things." (Interview 2)

> "The major centers generating the bulk of data are completely open as a result of their funding requirements to put the information into public databases, essentially, within 24 hours, so they do not even have time to mine the data if they wished." (Interview 6)

> "The real question is whether any publicly funded research should be protected? I don't think we should be patenting any of this stuff" (Interview 10)

Respondents noted that the goal of rapid dissemination, as mandated by the NIH, was more consistent with the public nature of their funding than the commercial imperatives currently advocated by the Canadian funding bodies.

> "For the tax payers to pay for tens of millions per project, it has to be open source ... . I think everyone is starting to see that it is actually better to have a scientific breakthrough that is on the cover of *The Globe and Mail* for Genome Canada than to have a patent that generates little or no revenue." (Interview 2)

> "The least open are the Canadian ones, specifically, the requirements of Genome Quebec, but worldwide, everything is open. The Welcome Trust and the Broad Institute put out primary data on the internet available to everyone, which is something we haven't done. I am sort of embarrassed that we haven't done yet because we are busy taking out patents, which is totally un-Canadian." (Interview 4)

> "The government, through the funding agencies and through the university, pays me to be a researcher and it is sort of my job to find things out and learn things ... so I don't know ... how far beyond that should I be able to take additional benefits?" (Interview 6)

> "Our research is paid by the government, we should share it freely. The amount of time a university or Genome Quebec puts in protecting IP which might only bring in a certain amount of money ... is not worth the time or effort." (Interview 8)

(i) Open Access Journals

When asked about experience with open source, most respondents felt the need to comment on the recent phenomenon of open publishing. While they were in favour of open access to publications, they questioned both the quality of these journals and the expense of publishing in them. In terms of quality, researchers felt comfortable publishing where the journal was reputable; however, in a number of instances they felt that open-access journals were of a lesser quality than more established publications.

> "I have been very disappointed with the quality of open access publications ... its almost impossible to reject something from there because it has to be bad science ... if it is boring, uninteresting if it is a very little advance in science, they will still publish it ... they have less academic weight than others and I think their impact is going down." (Interview 1)

> "We publish in both (open source and not open source) journals. It just depends on the quality of the journal ... with science, it is important to have it in a good journal. The better the journal, the better it is for your research." (Interview 8)

In terms of expense, it was noted that the high cost of publishing in a reputable open-access journal was seen as a deterrent for many researchers who would otherwise want to publish this way.

> "For most of the well-established ones you have to pay just to send your publication there ... so if you publish 5 or 6 articles a year that's 10 or 15 thousand dollars." (Interview 1)

> "I am all for open access but someone has to foot the bill. (When researchers have to pay) the money will be deducted from doing research to paying for open access." (Interview 4)

> "In the real world in small laboratories like mine, that (the money required to pay for open access to your publications) is the equivalent of hiring a summer student or paying part of a grad student's salary and those are real limitations." (Interview 7)

(ii) Should Genomic Research Always Be Freely Disseminated?

Respondents, for the most part, agreed that there was a benefit to sharing data generated from basic genomic research. In this respect, they saw open access to research results as an important factor in the progression of research.

> "I think open source is one of the best ways to actually leverage some discoveries quickly and to actually keep the basic science going." (Interview 2)

> "The best way to generate new hypotheses is to share the information." (Interview 3)

> "The type of science I am involved in requires the efforts of large teams and sets of teams ... the problems are too large and too huge for any of us to solve and it is not helping any one of us if we are not sharing our ideas." (Interview 6)

However, in the modern competitive research context, not all researchers thought that this sharing was justified. One researcher noted that the data generated through one's research is an important element in attracting talent to one's lab.

> "The benefit of keeping your data (private) is that it attracts good people. The competitive advantage comes from the people you work with, you get it from your ideas and you get it from the data you have access to." (Interview 10)

(iii) Successful Open Models of Collaboration in Biotechnology

Respondents noted a recent trend for research groups to make their results available online on a continual basis, on the condition that anyone working with the data allow the group generating it to have first publication rights.

> "I was working on analysis of part of the data (of fruit-fly genome) and we got a publication out of the analysis. There was a restriction that we could analyze the data any way we wanted to, but we could not publish our paper until the sequencing group had published their paper. I think it is a great way to go ... the other way would have been for them (the sequencing group) to hold back the data, which would have set everybody who was working on it back for a year or two of work. This way, everybody has their data and could get a head start." (Interview 1)

> "I think one way they can be protected is to put disclaimers in these open source sites. The association browser that NCBI has created gives nine months from publishing the data for the original people who made the study to exercise a right of first refusal to publish the results and after that it is free for other people ... ." (Interview 2)

> "I worked on the Human Genome Project and it was made completely clear that the sequencing we did today would be completely available tomorrow ... so we had no ownership, no control, and simply requested that anyone using the data would acknowledge that the sequence was generated by the project ... and a request that centers that generate the complete genome data have the opportunity to write the first publication of the genome wide analysis." (Interview 6)

(iv) Problems with Open Access Data

A problem noted with online results of open models of collaboration is that they could be less rigorously analyzed than those which are published with a longer delay in a peer-reviewed journal.

> "We thrive to get published in a journal as good as possible ... it shows your data is reliable. In open source if you give it away, it will demean your results and nobody would believe them." (Interview 8)

> "Open source can make a wider data source available but can also lock in a certain view of science ... . This group put their data on the website, but there were obvious flaws. Later they released version two of the data with a completely different analysis. The first was clearly wrong and the second analysis was much better. But after the first paper came out, many scientists and labs started working on some of the associations identified that were not real. In fact, less than 3% in the top 100 associations initially identified were real." (Interview 10)

One suggested way to improve this situation is to require groups to publish additional supporting materials with their datasets. The comparison was made to the software open source movement, where as versions are improved, creators can keep track of who made which improvements and when. In this sense, in order for a wider variety of people to learn

from the data, the researchers would have to disclose more about the evolution of the data from the outset.

> "If version two of a data set shows up on a website and without an explanation of what happened I didn't learn anything, I don't know what to trust ... they should provide support literature, quality control standards so that users will be safe using them." (Interview 10)

V. DISCUSSION

1. Publication Policies

Interviewees suggested that publication restrictions themselves do not pose much of a problem for their research. As a result of experience, these researchers and their funding partners have pragmatically resolved this issue by timing the review process with the writing process. Publication restrictions may thus not actually delay publications, because they are being edited and finalized at the same time as they are being reviewed.

While the enforcement of publication delays has not been identified as problematic by this group, negotiating acceptable delays before the research begins was noted to be a difficult aspect of concluding a research contract. A recent review conducted by the Canadian Association of University Teachers ("CAUT") revealed that university policies are inconsistent and permit delays between 12 and 24 months.[47] In addition, many have exceptions that allow these periods to be extended even longer. This creates ample room for funding partners to try and negotiate long delays, while researchers want to keep them as short as possible. To this end, the establishment of an acceptable publication-delay consensus, across all research institutions, would not only facilitate more rapid dissemination of research results, but it would also prevent time from being wasted in the negotiating stage.

Several organizations and coalitions have looked into this issue and have concluded that maximum publication delays should be imposed. For example, the CAUT recommends that universities adopt a uniform resolution guaranteeing that the maximum publications delays that they will accept will not exceed 60 days.[48] In their view, this is a sufficient

[47] Canadian Association of University Teachers, *The Freedom to Publish: CAUT Briefing to Academic Staff Associations* (Ottawa: CAUT, 2004), online: Canadian Association of University Teachers <http://www.caut.ca/uploads/brief_associations.pdf>.

[48] *Ibid.*

amount of time to secure intellectual property protection and the only justifiable infringement on the otherwise guaranteed freedom to publish.

Many other coalitions of universities, industries and researchers have worked together to develop similar policies. For example, the guidelines adopted in July 2006 by the Federation of American Societies for Experimental Biology ("FASEB")[49] suggest 30 to 60 days as the maximum amount of time that industry can review a publication before it is published.[50] While FASEB accepts that in extraordinary circumstances longer delays may be acceptable, it urges that these exceptions be worked out before the conclusion of the research contract. The Academy Health *Ethical Guidelines for Managing Conflict of Interest in Health Related Research* follow a similar policy. These guidelines advocate that all publication delays should be designated in the contract and that these delays should not exceed two months where possible, and at all times, not exceed six months after the research is complete.[51] The World Intellectual Property Organization guides universities to ensure that delays do not exceed six to twelve months, unless there is a "submission of a compelling case (by the research sponsor) and with the agreement of the research staff involved".[52]

An important aspect of these policies is that barring exceptional circumstances, maximum publication delays are imposed on all research contracts. In order to reduce pre-contract negotiations on this issue, these policies must be implemented. In order to have the greatest effect, they should be uniform across academia. How can this be accomplished? Indeed, a challenge we still face is that there is little consensus among the various agreements as to the duration of an acceptable publication delay. As such, it may not be reasonable to expect that the same policies be implemented everywhere. However, more interaction and discussion on these issues between various technology transfer offices, funding institutions, researchers and industry could lead to the adoption of more informally uniform approaches across various institutions. An important

[49] This federation is comprised of 23 organizations and has over 65,000 members.

[50] Federation of American Societies for Experimental Biology, *Shared Responsibility, Individual Integrity: Addressing Conflicts of Interest in Biomedical Research* (Bethesda: FASEB, 2006), online: Federation of American Societies for Experimental Biology <http://opa.faseb.org/pdf/FASEB_COI_paper_7x06.pdf>.

[51] Academy Health, *Ethical Guidelines for Managing Conflict of Interest in Health Related Research* (Washington, Academy Health, 2004), online: Academy Health <http://www.academyhealth.org/ethics/report.pdf>.

[52] World Intellectual Property Organization, *Guidelines on Developing Intellectual Property Policy for Universities and R&D Institutions* (Geneva: WIPO, 2004), online: WIPO <http://www.wipo.int/export/sites/www/uipc/en/guidelines/pdf/ip_policy.pdf>.

question left to discuss is thus: How can we encourage greater interaction and knowledge transfer between institutions?

2. Material Transfer Agreements

Both the literature review and the interview study denote problems with the material transfer process. While some interviewees recognized that in practice these strict requirements are somewhat relaxed, many still felt that the process of sharing materials in the university setting is in need of reform.

A significant problem arises when material transfer agreements are used when they are not necessary. As mentioned in the literature review above, they are often used by industry even where the materials have no commercial value and they are used by universities even where researchers want to freely share the materials they create.[53] These parasitic MTAs can cause delays in research while contracts are being negotiated and can even lead to the abandonment of a project because of disagreement over the terms.

While MTAs are necessary in some circumstances, their overuse can unnecessarily complicate the research process. To this end, it could be beneficial to develop guidelines on when MTAs should and should not be used. These guidelines could advocate a greater role for researchers in deciding how to transfer their materials, along with criteria for determining when an MTA would more likely complicate than complement the research process.

Recognizing the problematic effect of material transfers in research, the NIH in the United States developed a standardized MTA for signatories to use when transferring material within academia. The Uniform Biological Material Transfer Agreement ("UBMTA") was developed in 1995, and has since been adopted by 331 research institutions.[54] The benefit of this agreement is that it can "reduce transaction costs by reducing negotiation costs within communities that routinely use them and can facilitate regimes of frictionless exchange and reuse".[55] Because of the

[53] Katherine Ku, "Point: MTAs Are the Bane of Our Existence!" (2007) 25:7 Nature Biotechnology 721.

[54] Association of University Technology Managers, *FY US Licensing Activity Survey*, 2007, online: Association of University Technology Managers <http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm>.

[55] Thinh Nguyen, "Science Commons: Material Transfer Project" (2007) 2:3 Innovations: Technology, Governance and Globalization 137 at 140.

value of working on standardized terms, it would likely be beneficial for more members of the Canadian research community to become signatories to the UBMTA. As an alternative, the community may consider adopting a substantially similar standardized MTA fit for the Canadian context.

The commitment to use the UBMTA would be an excellent start; however, it may not be enough as "signatories can opt to use them on a case-by-case basis, and some institutions may include in these MTAs additional modifications that would render them non-standard".[56] In fact, it is acknowledged in the NIH Guide that the standardized agreement may not be suitable for every transfer.[57] Different circumstances may require different terms and when these terms are not familiar, the negotiation process is re-complicated. Additionally, a major drawback to the agreement's utility is that it only applies to public and non-profit material transfers. As such, it does not facilitate material transfer between industry and academia.

A novel solution to this problem is being developed by the Science Commons Material Transfer Project. The goal of this project is to put together a licensing model for biological material transfer that allows for customization, but at the same time provides "practical incentives towards more sharing on standardized terms".[58] For transfers between non-profit institutions, the project encourages researchers to use an unmodified UBMTA. In exchange for transferring materials on these terms, researchers are given access to tools and infrastructure where they can list, search and track the downstream impact of the samples that they provide.[59]

For transfers between academia and for-profit institutions, the project is developing a web-based modular contract, whereby the company can choose from a range of standardized terms to create MTAs that suit their needs.[60] This approach provides flexibility for the company, but at the same time limits its choice of terms to available options thereby preventing the inclusion of unduly restrictive clauses. Significantly, there are no options "that restrict publication or that contain reach-through

[56] *Ibid.*

[57] National Institutes of Health, "Uniform Biological Material Transfer Agreement Finalized" (1995) 24(14) NIH Guide, online: National Institutes of Health <http://grants.nih.gov/grants/guide/notice-files/not95-116.html>.

[58] Science Commons, *Empirical Data About Material Transfer Problems*, online: Science Commons <http://sciencecommons.org/projects/licensing/empirical-data-about-materials-transfer/>.

[59] Thinh Nguyen, "Science Commons: Material Transfer Project" (2007) 2:3 Innovations: Technology, Governance and Globalization 137 at 140.

[60] *Ibid.* at 141.

royalties, grant-backs, commercialization options, or other obligations with regard to downstream inventions made by the recipient".[61] In addition, in order to facilitate the use of the different options, each MTA would be accompanied by a "human readable deed" that explains the meaning of each contractual clause in lay terms, thus making any deviation from the standard contract "immediately obvious".

The prime incentive for using this model from an industry perspective is that it would increase their ability to share materials. When materials are transferred through this process, they would be tagged with Science Commons MTA and searchable online by researchers looking for materials. The key advantage of the system is that researchers would know, in advance of designing their protocols, which materials were available and on what terms. The idea envisaged by the Science Commons is that with standardization, web-based material transfers could take place with the same ease and speed with which one now can purchase a book in an online bookstore.

Negotiating MTAs is a significant source of delay in the research process. As outlined above, there are many proposals to reduce the negative impact of MTAs. In particular, two areas where more discussions may be needed in the Canadian research context are the creation of guidelines on the use and non-use of MTAs and the promotion of standardization within the MTA process. Questions to consider could include: When should MTAs be used? When should they not be used? Is standardization the answer? Which terms should be standardized and who should decide? Does the UBMTA need to be modified for the Canadian context? Will the Science Commons project sufficiently fill the gaps in the UBMTA and does it provide sufficient IP safeguards to be widely accepted by industry?

3. Students and Conflicts of Interest

Prior to the commercialization of academic research, the academic researcher's primary responsibilities were to teach and conduct research. These goals were non-conflicting. However, the introduction of commercialization into that relationship may lead to situations of conflict that ought to be addressed. In particular, is it appropriate for students to work on projects with commercial elements? While some of the researchers

[61] *Ibid.*

were adamantly opposed to it, others felt that training students on commercial projects could be accomplished in a non-conflicting way.

Most, if not all, universities have guidelines about conflicts of interest and students. Some are extremely comprehensive. For example, Harvard's *Policy on Conflict of Interest and Commitment* requires researchers to ensure that any contract terms "that inhibit scientific communication or that commit intellectual property rights to the industrial sponsor" do not adversely impact their students.[62] The policy also outlines specific disclosure requirements for researchers to inform students about the source of their funding, any financial interest they may have in the research and any potential restrictions on communication of the data. It also provides an appeal mechanism for students to switch projects when they believe their training is being compromised by commercial conflicts.

Not all policies are this comprehensive. For example, McGill University's *Policy on Ethics in Research and Research Training* is much more general in its obligation, as illustrated in section 3.7.2, which states that "both mentors and trainees should declare to each other any conflict of interest that may pertain to their mentor/trainee relationship".[63] The policy also affirms a general commitment to the academic objectives of "research, the training of students, and the advancement and dissemination of knowledge".[64]

Should conflict of interest policies be specific or general? In order to reach the point where solutions can be discussed, more data concerning the magnitude of this problem and the effectiveness of the policies currently in place is needed. Key questions that ought to be addressed include: Are general policies on conflicts of interest sufficient? Should researchers be prevented from entering contracts that would prevent students from presenting and publishing research results? Provided there is sufficient disclosure, should students be permitted to train on commercial projects that may impose presentation and publication restrictions on them? What can be done to raise awareness of potential conflicts of interest in commercialized academic research?

[62] President and Fellows of Harvard College, "Policy on Conflict of Interest and Commitment" in *Faculty Policies on Integrity in Science* (Boston: Harvard, 1996), online: Harvard Medicine <http://www.hms.harvard.edu/integrity/conf.html>.

[63] McGill University, *Policy on Ethics in Research and Research Training* (Montreal: McGill), online: McGill <http://www.mcgill.ca/researchoffice/policies/sponsored/policies/training/>.

[64] *Ibid.*

4. Open Access for Publicly Funded Research

Many of the interviewees felt responsible to the Canadian taxpayers who fund their research. They felt that Canadian funding policies were sometimes at odds with the current trend towards open access advocated by both the NIH in the U.S. and Wellcome Trust in the U.K. For example, as of January 25, 2008, the NIH requires that all NIH-funded genome-wide association studies ("GWAS") submit their results to the GWAS data repository.[65] The policy recognizes that "the full value of GWAS to the public can be realized only if the resulting genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators". Similarly, the Wellcome Trust policy requires that "sequence assemblies should be released as soon as possible; in some centres, assemblies of greater than 1KB would be released automatically on a daily basis. Finished annotated sequence should be submitted immediately to the public databases".[66] (The NIH and the Wellcome Trust have since modified their policies for posting and accessing GWAS data contained in their databases. Both have removed some aggregate data from public availability in response to the publication of new statistical techniques for analyzing dense genomic information that made it possible to infer group assignment of an individual DNA sample under certain circumstances.)

While Genome Canada's 2005 Data Sharing Policy advocates that researchers should deposit data into international data repositories,[67] some of the researchers interviewed mentioned that they had been prevented from making their preliminary data available. While we did not conduct enough interviews to draw conclusions, this raises concern that in practice may still be preventing this policy from being truly effective. It would be interesting to see whether this tension between policy and practice is prevalent in other funding bodies as well.

[65] National Institutes of Health, "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)" (August 28, 2007) NOT-OD-07-088, online: National Institutes of Health <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

[66] Wellcome Trust, Statement on Genomic Data Release (Bermuda: Wellcome Trust, 1996), online: Wellcome Trust <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002751.htm>.

[67] Genome Canada, Data Release & Resource Sharing Policy (Ottawa: Genome Canada, July 1, 2005), online: Genome Canada <http://www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf>.

The benefits of open models of collaboration have been expounded in many texts.[68] "Scientific progress and public benefit will be maximized by early, open and continuing access to large data sets and by ensuring that excellent scientists are attracted to the task of producing more resources of this sort."[69] However, there have also been some criticisms of this system that ought to be addressed.

First, many have questioned the impact that immediate open access to results will have on the publication process. In particular, how will researchers be recognized for their contributions if other researchers are free to publish using their results? Many open-access projects have dealt with this concern by creating a period of exclusivity within which the sharing investigator can sufficiently mine and analyze the data for publication. A significant advantage of this approach is that while publications of results may be held back, the research itself is not being delayed. After the exclusivity period has elapsed, the researchers working with the data are free to publish right away. Indeed, this model has been used by large-scale open-source projects, such as the Human Genome Project, where information was put online daily on the condition that the investigators working on the project would have the right to publish the first genome-wide analysis using the information.[70] The new NIH policy also gives a maximum of 12 months of exclusivity before others are free to publish manuscripts based on data obtained from the repository.[71]

Second, open-access data repositories have been criticized as being questionable resources, as it is difficult to judge the validity of data from the partial information contained therein.[72] This criticism, however, goes more to the quality of such repositories and not to the process of open dissemination itself. As such, one solution to this problem would be to encourage greater transparency in sharing, greater standardization in reporting criteria and more critical methodological standards across repositories. For example, the NIH policy requires that investigators

[68] Yann Joly, "Open Sources Approaches in Biotechnology: Open Source Revisited" (2007) 59:2 Maine L. Rev. 386.

[69] Francis S. Collins *et al.*, on behalf of the U.S. National Human Genome Research Institute, "A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era" (2003) 422 Nature 835 at 846.

[70] Francis S. Collins, Michael Morgan & Aristide Patrinos, "The Human Genome Project: Lessons from Large-Scale Biology"(2003) 300 Science 286 at 288-89.

[71] National Institutes of Health, "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)" (August 28, 2007) NOT-OD-07-088, online: National Institutes of Health <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

[72] Interview 8 and10.

submit "the protocol, questionnaires, study manuals, variables measures and other supporting documentation".[73] In addition, "the NIH strongly encourages the submission of curated and coded phenotype, exposure, genotype, and pedigree data, as appropriate, to the NIH GWAS data repository as soon as quality control procedures have been completed at the local institution".[74]

While the quality control aspects of open models of collaboration in biotechnology are in need of strengthening, the advantages of ensuring that genomic research data is made publicly available have been recognized by important genomic funding bodies in the U.S. and the U.K. The question remaining is why has it not yet been recognized in Canada? Should the primary goal of publicly funded research be the rapid open dissemination of data? Is this in fact the best way to ensure that the maximum value is extrapolated from every research dollar? Finally, what is the best way to encourage standardization in reporting criteria so that the information itself becomes more valuable?

VI. CONCLUSION

Commercialization plays an important role in the modern technology transfer process. However, as commercial goals permeate academia, it raises many questions about the various conflicting interests that may arise. The available evidence suggests that a consequence of the commercial shift is increased secrecy, resulting in raised research transaction costs, delays in the publication and presentation of research results, and an overall decrease in the morale of the scientific community. As such, many have called for a change in the way that academia is approaching its role in commercialization.

But how does this evidence measure up to the experiences of genomic academic researchers? Through a qualitative study, we have attempted to present a more informed view of the impact of commercialization in academia. This research could assist in generating much needed discussion concerning the commercialization of academic research in Canada. We conducted ten qualitative interviews with fundamental genomic researchers, from various disciplines. A convenience sample was

[73] National Institutes of Health, "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)" (August 28, 2007) NOT-OD-07-088, online: National Institutes of Health <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

[74] *Ibid.*

selected, and each member was individually asked a series of semi-structured questions about commercialization and research, research policies and open source. A major limitation of this methodology is that little generalizable data may be extrapolated from the results. Nonetheless, the personal experiences of these researchers enabled us to focus our discussion in a way that may be more reflective of the changes that researchers have perceived due to the commercial shift in academia.

The interviews led us to focus on four important points and to suggest specific options for future discussion. First, we explored the role of publication policies and the potential impact they have on research contracts. We felt that greater collaboration was necessary so that maximum publication delays could be more uniformly applied. Second, we explored the material transfer process and suggested that guidelines on the use and non-use of material transfer agreements could lead to more openness and sharing within the academic community. We also explored various standardized MTA agreement options and questioned whether there was a place for these options in the Canadian context. Third, we questioned whether conflict of interest policies dealing with the inclusion of students in commercial projects were sufficiently useful and specific. Finally, we discussed the open-access policies for publicly funded research in other jurisdictions and questioned why Canada's funding organizations did not yet follow similar policies. We noted that there was a need for more discussion concerning the standardization of reporting criteria so that these tools would be maximally valuable.

This study is only a first step that could provide a starting point for a much needed Canadian debate on the commercialization of academic scientific research. Further reflection on these issues could contribute to the creation of more balanced technology transfer policies so that the interests of academia are not lost in the process of commercialization.

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