# Impact of the Commercialization of Biotechnology Research on the Communication of Research Results: North American Perspective

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## Abstract

Evidence demonstrates that academic biotechnology research has become increasingly commercial in the last twenty years in Canada and in the US. This article demonstrates the existence of a significant correlation between commercialization and withholding of information in biotechnology research conducted in these two countries. It then attempts to find out where and how, in the commercialization chain, the free dissemination of information could be put in jeopardy by commercial pressures.

The tension between private interests and professional duties may create conflicting interests. In biomedical research, increasing university-industry partnerships have raised concerns about the possibility that academic free-

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dom, research integrity and the advancement of science might be jeopardized by overarching commercial pressures. These pressures have become more pronounced as investment in research and development has increased to promote the economies of developed countries.

Over the years, legislation and policies have encouraged private investment in universities so as to derive maximum profit from one of the most valuable contemporary assets: knowledge. However, as government funding of research declined, industry sponsorship filled the gap. In this context, the goals of academia and those of the industry have become complementary.

This relationship is profitable for industry due to patents on fundamental discoveries. Laws in an increasing number of developed countries are introduced to allow inventors to patent and to strengthen the level of intellectual property protection. Through sponsorship agreements, universities grant commercial biotechnology companies exclusive licenses to transfer fundamental knowledge to the commercial sector. In exchange, the university receives funds for the research and the patent holder receives royalties that go towards the laboratory expenses. This system works because it allows companies to maintain a competitive edge by gaining access to cutting-edge research, while providing universities an additional source of income to supplement public funding.

However, empirical studies show that this industrial drive has created a situation where university researchers are increasingly subservient to industrial interests. Pressures placed on academics to follow the wishes of sponsors could undermine the academic value of open science in favor of commercial interests. In other words, has this commercialization model created a climate favorable to the development of conflicts of interest? Have academics been placed in a situation where financial and other personal considerations could compromise or have the appearance of compromising, their professional judgment in the communication of research findings? This article will first review the available evidence of such conflicts within the American and Canadian biotechnological academic communities and then examine the sources of secrecy within the technology transfer process. While industry sponsorship is without doubt an important contribution to the advancement of biotechnology research, universities must create proper procedural safeguards to ensure that academic freedom and integrity are adequately protected in the process of commercialization.

# PART 1 – COMMERCIALIZATION AND DATA WITHHOLDING

## The Commercialization of Biotechnological Research: American Landscape

In a knowledge based economy, economic growth is promoted in part through increasing rates of public and private investments in research and innovation. As leaders in this trend, American universities recognized the commercial potential of university research as early as the 1920s. By the 1970s an increasing number of universities began to actively manage their intellectual property. However, at this time,

there was no uniform policy governing the ownership of university research proceeds. Thus, government funding agencies were unable to successfully commercialize this research.

In the 1980s the adoption of a new simplified legislation on technology transfer allowed for "a greater flexibility in negotiating licensing agreements." It motivated universities to patent and license their discoveries to private firms and made it more desirable for firms to collaborate with universities through the newly facilitated channels. After intense lobbying by both the US public and private sector, the Bayh Dole Act was passed. Commercialization was promoted by vesting proprietary rights in universities thereby ensuring that proceeds from inventions would be shared amongst the inventor and the institution. In addition, the Stevenson-Wylder Act of 1980 gave federal funding agencies the power to offer both exclusive and non-exclusive licenses to private organizations to encourage the commercialization of university technology.

In the early 1990s cutbacks in corporate science spending caused firms to reorient their business strategies and intellectual property policies. Company labs became smaller and more decentralized. Scientific and business decisions became associated with their corporate strategic planning and companies began to prioritize R&D in order to remain competitive. As a result, many large R&D firms turned to contracting with universities in order to gain new knowledge critical to their innovation capabilities.

Universities and industry used intellectual property to capitalize on innovation and attract further private investments. This served as an incentive for large biotechnology companies to invest in university research so as to widen their product lines. As a result, the gap between the "grand dichotomies" of the public and private realms shrunk. At the time of the commercial trade, valuable research assets became increasingly important for universities due to decreasing public investment. The "social contract" between science and society was rewritten as universities became obliged to change their policy framework in order to embrace their new role "as entrepreneurs of knowledge." The landmark Diamond vs. Chakrabarty US Supreme Court ruling confirmed the patentability of biotechnological innovations, which subsequently allowed industry to protect and strategically capitalize on a greater range of university discoveries.

Today, the rise in patenting and intellectual property management by universities demonstrates the growing role of technology transfer offices in commercializing faculty inventions. Industrial resources funded 7% of total research expenditures amounting to $42.3 billion in 2005. In 2004, the Association of University Technology Managers AUTM reported approximately $249.4 million of industry funding in exchange for license/option agreements. Moreover, it was observed that when academic researchers were exposed both to the technology transfer operations and to their colleagues' commercialization initiatives, the former engaged in more patentable disclosures to the university technology transfer offices. In 2005, 191 American universities recorded 17,382 invention disclosures as opposed to 9,669 in 1996. 83.8% of these disclosures contained potentially patentable ideas. The ratio of new US patent application to invention disclo-

sures had increased from 26% in 1991 to 59%. 10,270 new US patents filed were filed by 191 institutions in 2005, an increase from 2000 where 6,073 had been filed by 167 institutions. Increased licensing was attributed to the increase of faculty and administrator willingness to license as well as to external research and development. 158 respondents reported 4,201 licenses/options were executed in 2005; this is an increase since 2003. For every disclosure to the university technology transfer office, a license/option was executed, demonstrating that technology was successfully being transferred to firms.

The Universities' tendency to increase patenting and the licensing of their innovations suggests that American universities have continually growing commercial interests. Thus, academic researchers could be propelled to act accordingly by withholding research results.

## The Withholding of Research Results: American Overview

Academic researchers have a responsibility to advance knowledge through the dissemination of their work. They have the right to freely pursue research without unjustified interference but also the commensurate duty to publish and communicate their conclusions. Institutions of higher education are presumed to serve the common good and create an environment that promotes the search for truth and its diffusion.

Yet, freedom in the academic environment has waned as universities have shifted their policies to accommodate commercial interests without creating proper procedural safeguards. Other than a non-specific statement that publications should not be delayed longer than needed to obtain intellectual property protection, a majority of US universities do not set a maximum acceptable delay for the communication of research results. This type of clause might be insufficient to ensure the efficient and timely dissemination of research results as it does not seem to preclude companies from securing secrecy by other means throughout extended technology transfer processes.

Blumenthal observed that industry support is associated with a decrease in publication rates. Conversely, he also demonstrated that researchers with minimal support from industry could maintain a high publication rate. A significant percentage of researchers with industry funding were found to delay publication of research results for more than 6 months. Data withholding was found to be especially prevalent in the field of genetics: geneticists with a patent application, whether issued or licensed, a product on the market under review or a start-up company were associated with a greater incidence of verbal withholdings.

The US Patent Act limits the period of secrecy by mandating the publication of all pending patent applications after eighteen months. In terms of visibility and accessibility of potentially useful information this kind of disclosure is not the same as full disclosure of an invention in a scientific journal. According to Eisenberg, disclosures made in scientific publications still lacked full disclosure of raw data associated with the discoveries. The affirmation that academic patenting negatively impacts the rate and quality of publications in the US is contested by the result of a recent econometric study by Azoulay, Ding and Stuart. However, this study does not consider the

influence of academic patenting on publication delays and thus seems to overlook and important element of the equation.

As noted, changing policies and the fact that firms increasingly outsource their industrial R&D to universities stimulated universities to commercialize. However, American universities have adopted the commercialization model more successfully than universities of any other developing countries. In addition, reinforcement of intellectual property protection provided for the safe trading of these intangible assets through licenses and ultimately led to greater revenue for American universities.

## The Commercialization of Biotechnological Research: Canadian Landscape

In contrast to American universities, Canadian universities in the early twentieth century maintained that teaching was their only legitimate activity. All universities were publicly funded and federal intervention was strictly limited to the extent of federal funding because university matters were confined to provincial jurisdiction. Academic freedom flourished while universities showed little interest in commercial activities. This disinterest for commercialization can be attributed in part to the lack of a national policy for commercialization at the time. Canadian universities maintained this open science culture throughout most of the twentieth century.

In the 1980's, three types of federal institutional support were created to promote corporation-university linkages. The federal government used the influence it had gained on research through policy guidance and funding control over major research councils to promote research commercialization. It also created third party networks to foster the creation of partnerships. These organizations, such as the Science Council of Canada, included representatives of business, universities and government to represent the interests of Canadian society. The recommendations made often favored a corporate agenda for universities. Finally, the government created the Network of Centers of Excellence. These centers had the goal of fostering a more collaborative model of innovation to ultimately create a national research capacity that would be responsive to the needs of both industry and economy. They were conceived to "float on top" of existing structures. In this way, the federal government circumvented the power of universities, the autonomy of researchers and provincial jurisdiction to thus eliminate barriers to the creation of a national model of research and development.

While the government succeeded in creating structures to promote university industry linkages, it did not manage to convince universities to take a more active role in the research commercialization process. Canadian universities still employed their individual ownership policies making commercialization negotiations difficult and time consuming. The government then realized that the laissez faire approach resulted in lost commercialization opportunities. So it tried to use the American Bayh Dole method by recommending that universities now include "innovation" as part of their mission. The government also tried to motivate universities to implement incentives such as royalty-sharing and recognition in order to promote disclosure of research with commercial potential. However, unlike the Bayh Dole Act, the Canadian recommendations did not include

an (implicit) obligation to commercialize. Therefore, Canadian universities continued to escape the pressure of commercializing research.

Universities began to acknowledge their part in generating economic wealth when they agreed to the Framework Agreement on Federally Funded Research in 2002. In this Agreement, the Association of Universities and Colleges of Canada stated that it would double the amount of research they performed and triple their commercialization outcomes by 2010.

However, serious impediments to research commercialization still lingered by 2004. The lack of an innovation policy and model university-industry agreements, such as the ones created by the NIH in the US, raised the cost of technology and knowledge transfer. The lack of harmonization between granting agencies' and universities' intellectual property policies remained. Federal granting agencies, provincial granting agencies, universities, technology transfer offices and venture capital firms all used their own internal intellectual property practices. Provincial initiatives then began to coordinate intellectual property policies within their respective jurisdictions. However, each agreement still had to be renegotiated every time, thus increasing the length of time and labor needed.

The lack of clear goals in Canadian innovation policy was considered to be a significant obstacle to technology and knowledge transfer in Canada. The federal government tried to resolve this issue by imposing a new mandate on the federal funding agencies and on the research granting councils (e.g., Canadian Institute of Health Research and Genome Canada) in 2000. Grants would now be issued based on an assessment of economic and social benefits to Canada as well as based on the number of patents held by the investigator. Also, in 2005, an expert panel on commercialization recommended that a Commercialization Partnership Board (CPB) be established in order to advise the Minister of Industry and to ensure that the private sector would assist the government in designing policies to improve commercialization.

Despite the fact that Canada's attempt to create a policy framework to promote commercialization in universities is more recent than that of the US, an impressive progression towards technology transfer is nonetheless noted. Canada has the second highest rate of private investment in universities of all of the G7 countries. Between 1996 and 2006, private investment in university research grew by 168%.

Universities have also increased their capacity for commercialization through significant investments in changing their infrastructure: technology transfer offices and associated activities have been implemented into their framework. The total income from commercialization of university research was twice as high in 2005 than in 1999. In 2004, 76% of institutions were managing their own intellectual property, an increase of 4% from the previous year. Between 2003 and 2004, the total number of research contracts rose by 25%. The value of these contracts also increased by 16%, from 810.4 million to 941.0 million. Of the 119 institutions surveyed in 2004, 72% reported their involvement in research contracts with industry, most of which included an option to acquire a license to the IP under commercially reasonable terms. Between 2000 and 2005, the number of inventions

reported or disclosed to university technology transfer offices increased from 957 to 1,433. The number of new patents applications filed increased from 240 in 2000 to 685 in 2005 and the trend is expected to continue in the next five years. By the end of 2004, 50% of all patents obtained in Canada had been licensed, a 15% increase since 2003. Despite this rapid growth, Canadian universities still lag behind the US in their licensing revenues.

## The Withholding of Research Results: Canadian Overview

Through commercialization policy initiatives and the recent acknowledgement of the economic role of universities, the Canadian government's push to increase commercialization of university research has created conditions that are propitious to greater secrecy in university research. Similarly to the US situation, the majority of Canadian universities intellectual property policies fail to impose firm publication delays. Delays range from three to twenty-four months but can usually be extended for an undetermined duration if necessary.

Canadian case law also suggests that industry is using contractual means to prevent the disclosure of research results so as to protect its commercial interests. In these cases, drug companies attempted to control the publication of results, withheld data from publication and permitted only partial disclosures of results in scientific publications. For example, in 1997, Brystol Myers Squibb Inc. sued the Canadian Coordinating Office of Health Technology Assessment in an effort to prevent the release of a summary report on Statin drugs based on a technical review of published clinical trials and pharmacoeconomic evaluations. The company's main concern was economic. It feared that the release of the report would motivate the provincial governments to "… turn to the cheaper medication rather than to the more established and proven medication." While the court refused to grant a permanent injunction, the publication of the report was delayed for almost a year.

Another example is the case between Apotex Inc. and the University of Toronto. A researcher, Dr. Nancy Olivieri had signed a clinical testing contract with Apotex Inc. This contract included a confidentiality clause granting Apotex Inc. the right to block the communication of research data for a year after the termination of the trial. During the course of her study, Dr. Oliveri found that the drug did not show any significant improvement over the treatment of thalassemic patients. However, she decided not to disclose the situation to the patients after Apotex Inc. threatened her with legal action if the information was revealed. This situation brought to light the dangers of commercial pressures in the clinical research setting. This case led the University of Toronto and its seven affiliate teaching hospitals to implement a new policy whereby contract research agreements could not censor or delay publication for more than six months.

The Canadian government's initiative to promote technology transfer within universities is still in its early stages. However, evidence of the suppression of data already exists in the clinical setting. Canadian universities and government need transparent and coherent innovation policies. They must also monitor increasing academic-corporate linkages that might be putting

Canadian institutions in a situation where the timely disclosure of information cannot always be secured. Therefore, the high investment rate of private investment in Canadian universities, increasing number of agreements with industry and the fact that the majority of provisional patents are being filed in the US lead us to believe that parallels can be drawn between the Canadian and the US experience with respect to secrecy in the research sector.

# PART 2 - SOURCES OF SECRECY IN THE NORTH AMERICAN TECHNOLOGY TRANSFER PROCESS

Three situations affect the commercialization of research and the possible degree of control over publication that a sponsor can exert over a researcher. First, influence is limited when research is government funded. Second, the sponsor exerts a greater degree of control on the research via a contractual engagement. Third, the researcher is hired as a consultant whose expertise is considered as know-how by the sponsor. As will be explained further in this part, in this last situation, the distinction between a researcher in industry or academia seems the most confounded.

## Government Funded Research

Even when research is funded almost entirely from public sources, publication delays exist. For example, geneticists working on publicly funded research projects have been found to have withheld data from their colleagues at different stages of research and commercialization: such behavior was noted when patents were applied for, and when patent applications were under review. Once patents were issued and licensed, secrecy was evidenced both when a product was put on the market and also when a company was starting up. This drive to commercialize federally funded research is both the result of government strategies to maximize R&D and the changing academic environment. It has the side effect of motivating researchers to withhold information.

In the US, the Bayh Dole Act implicitly obliges universities to commercialize federally-funded innovation. The Act allows universities to retain ownership over research results that were in full, or in part, federally-funded. The Act also directs that "contractors who elect title to the subject invention 'agree to file a patent application prior to any statutory bar date'." The university co-contractors must therefore commercialize their inventions in order to retain title. If they fail to do so, then the federal government reserves the right to assume ownership and to either require the contractor to grant licenses or, in the case of refusal, grant licenses in the contractor's place.

Similarly, in Canada, commercialization mandates are given to federal granting agencies such as Genome Canada, a not-for-profit corporation that invests in partnerships between provinces in order to support genomic research. For these partnerships to obtain financing, solid evidence of the anticipated social and economic benefits of the project must be put forth. Moreover, Genome Canada's research projects must not only implement mechanisms of patent protection in accordance with both federal and provincial laws, but also "[not limit] the execution of non disclosure and confidentiality

covenants by employees of participants (private sector companies, universities, and hospitals)" during the research period. Finally, although Genome Canada does require that all patentable data be disclosed by the date of patent filing or the date of the provisional patent filing, there are still situations where it is possible to delay data release beyond that date with Genome Canada's permission (e.g., when patents are involved). Thus, much like the American research framework, the researcher is placed in a difficult situation: in order to obtain federal research funding, intellectual property potential must be protected.

Researchers are generally more inclined to submit their research for licensing where the university has an established technology transfer operation or where others in the same academic rank also disclose information. In addition, university technology transfer offices encourage researchers not to present or publish their results until a patent application is filed and a licensee for the invention is found. Generally, in order to be patentable, the subject matter defined by the patent claim must not have been previously disclosed to the public. However, in Canada and the US, there is a grace period allowing an inventor to file for patent protection within one year after a public disclosure. Surprisingly, this grace period does not appear to have promoted a greater rate of publication. This is because it is not uncommon for a year to pass before fundamental research results are patentable and also due to the significant delays caused by university technology transfer practices. Researchers are concerned with maintaining the novelty of their inventions in order to secure patents. Thus, despite the existence of this grace period, most institutions will not take the risk of disclosing prematurely.

In many situations, universities will opt to protect their work by filing provisional patent applications since their inventions are basic and their potential for commercial success is still hard to determine. Provisional patent applications allow universities to evaluate whether the inventions are worth the financial investment represented by the patenting process. In the US, filing a provisional patent will give the university technology transfer office an additional twelve months beyond the grace period in order to assess whether the invention is commercializable and whether the filing of a patent application is cost effective. Another advantage of filing a provisional patent application is that it is not published after the eighteen month period. Therefore, in an extreme case where the university does not establish a clear publication delay, publications could be delayed for an additional eighteen months after the end of the twelve months attributed to the provisional patent. These advantages make provisional patent filings attractive to universities: new provisional patent applications constituted 69.9% of all new patent applications filed in the US in 2005. In Canada, 64% of patent applications were US provisional patents in 2004 that were subjected to the same process and delays.

Licensing practices have also been found to restrict the dissemination of research results. License terms such as royalty rates and publication delays are negotiated between both parties. A recent survey established that approximately 27% of university licenses included clauses allowing for the deletion of information from papers before submission. 44% of licenses asked for publication delays of an average of four months. Moreover, since licensing rights

relating to the intellectual property will usually cover information that is too premature for commercialization, and since this information is easy to reverse engineer, licenses usually require that the surrounding know-how also be kept secret.

In short, obligations attached to government research grants have left the researcher in a situation where he is obliged to conform to the commercialization process in order to get government funding for his research. The delays inherent to the patenting process will also hinder the rate at which information becomes public. Moreover, when research is funded by the private sectors through sponsorship agreements, additional obligations satisfying corporate strategies are imposed on the researcher receiving the funds in addition to patent application delays.

## Sponsorship Agreements

The majority of funding from private biomedical companies is directed towards fundamental research with commercial potential. In this type of collaboration, the university produces basic knowledge while the sponsor develops it. However, researchers who ultimately obtain funds are likely to be imposed significant restrictions with respect to communicating the results of their research. These restrictions target both verbal and written communications and are intended to give the company time to successfully transfer the technology to the market. Indeed, of 200 contracts analyzed in one American study, only 19% of the sponsoring firms delayed publication of research results.

With the proper protection of exclusive sponsorship agreements, investors will be more prone to invest since the threat of imitation and knowledge spillover becomes limited. In these agreements, sponsors will attempt to retain certain rights to proprietary information and the first rights of refusal in order to have a competitive advantage in the commercialization process through patenting or other means should they so desire.

Several factors influence the degree of secrecy imposed on the academic research project. One such factor is the prestige of the contracting university. Less established universities in greater need of private funds will usually allow for greater publication delays, while more respected institutions with more public funding will be in a stronger position to negotiate. Large publicly funded organizations like the National Institutes of Health (NIH) exert more control over their research and are therefore able to avoid long publication delays. Similarly, the prestige of the principal researcher is inversely correlated with the influence that industry will be able to exert. Industry sponsors appear to be willing to sacrifice some control for the added benefit obtained by working with renowned scientists. Furthermore, the size of the sponsoring company will affect the delays imposed in the contract; smaller companies usually have less bargaining power, which results in a lower ability to obtain publication delays.

The duration of the research project also influences the imposed publication restrictions. Longer projects usually entail a greater investment by companies and therefore a greater commitment by the researcher. Sponsors will thus include contractual clauses restricting the researcher from publishing partial results to ensure that the full value of the final results may be captured before it leaks into the public

domain. For example, in the case of genomic research, this can be accomplished by keeping the information protected as trade secret via contractual agreements until the innovation is complete enough to file a patent application.

The purpose of publication delays is to give the sponsors' personnel time to examine the researcher's manuscript to determine whether it contains patentable material. The delay is generally around forty five days. If the subject matter is patentable, the information will be removed from the manuscript, or the researcher will be asked to suspend the submission for publication until the patent is filed (or, sometimes, until a later date).

Sponsored research agreements will usually contain a clause specifying that disclosures made to the technology transfer office will be kept in confidence except with respect to the sponsor. Many life science firms require information to be kept secret for more than six months while they decide whether to patent it or maintain it as a trade secret. The reason for keeping the information confidential during this period is to prevent the novelty of the research from being jeopardized. These publication delays will usually be added on to the previously mentioned patenting delays in order to maximize the period of secrecy.

### Consultation Agreements

In this popular type of arrangement, the investigator transfers private technical information, such as know-how, to the industry in exchange for a monthly fee. This type of relationship is known to be the cause of some withholding of data in presentations and publications. In some instances, publication delays of more than ninety days were imposed on investigators. When the researcher is placed in this situation, the distinction between the researcher as a university researcher and the researcher as an employee of a company is practically non-existent; the university does not have any intellectual property rights to the knowledge since the researcher is subjected to company policies. Thus, consultation agreements significantly diminish the degree of control universities may exercise both on the knowledge as well as on publication delays.

## SUMMARY

Evidence demonstrates that academic biotechnology research has become increasingly commercial in the last twenty years in Canada and in the US. This obvious realization does not only carry negative implications. Private funds have helped American universities remain on the cutting edge of scientific research and provide the best learning environment for their students. However, it would seem that this increasing emphasis on research commercialization has also created situations where university teachers and researchers could now find themselves in conflict between their traditional academic duties and the new commercial imperatives. This situation is especially worrisome in that it could lead researchers to delay the communication of important findings over substantial periods of time in order to protect commercial interests.

In our article, we first demonstrated the existence of a significant correlation between commercialization and withholding of information in the biotechnology re-

search field in Canada and in the US. We then set out to find where and how, in the commercialization chain, the free dissemination of information was put in jeopardy. We conclude that policy changes may be required to improve the free flow of information. But, such policies must remain attentive to the new commercial obligations present in the technology transfer process. In the meantime, a greater harmonization and transparency of the publication policies and guidelines of the various actors would strengthen the bargaining position of researchers and universities in their negotiations with granting agencies and the private sector. Achieving fixed delays and controls would be an important first step toward a more "open" scientific environment.

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