

Material Transfer Agreements: A Review of Modes and Impacts¹

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ABSTRACT *Sharing or exchanging research material is typically formalised through material transfer agreements. The aim of this article is to put into critical perspective the empirical findings on modes and impacts of these agreements vis-à-vis commonly accepted concerns formulated in a Mertonian fashion for the case of academic science, and from the perspective of the anticommons theory for the case of academic commercialisation. Empirically, scholars have used statistical evidence in surveys of perceptions and dedicated measures through bibliometrics to study these agreements. These statistical studies have thus helped make progress in the understanding of the mode and impact, but such implications need to integrate diverse results from anecdotal evidence that is currently considered separately.*

Keywords: sociology of science, economics of science, intellectual property rights

1. Introduction

Sharing and exchanging research material is currently formalised through material transfer agreements (MTAs). Whilst there exist other contracts that can be used for such exchange and other strategies to gain access to research material, MTAs were pioneered by industry, and are currently widely used in academia. Moreover, MTAs are also used for commercial or safekeeping purposes (e.g. storage in gene banks).² The University of Pennsylvania was processing nearly 500 MTAs per year by 1999,³ and the University of California arranged approximately 2,000 MTAs in 2002.⁴

The use of MTAs for research purposes has generated a series of issues in academic circles that deal with protracted negotiations, terms and conditions (reach-through provisions, royalties and fees, publication restrictions and conflicting obligations with funding bodies), all of which have impacts on scientific research and commercial endeavour. Accordingly, it was feared that MTA negotiations may stifle the normal development of research projects in due course, or that MTA clauses may restrict the broad dissemination of new discoveries, slow down

the technology transfer process and limit future avenues of research and product development.⁵

Substantial research efforts have been devoted to gathering statistical evidence to study MTA modes,⁶ and their impact on science,⁷ or commercialisation.⁸ By taking into account existing empirical literature, it is intended to show how two crucial questions have been treated by scholars and policy makers, viz.: are MTAs harmful or innocuous for scientific research and commercial endeavour? Do MTAs used to govern the transfer of tangible research materials impede scientific progress and cumulative innovation? More formally, this article aims at producing a survey of existing literature on the interaction between contractual rules (MTAs) and norms. Two key messages which come out of this survey seem really worth mentioning: first, the ambivalence of MTAs in regards to hampering or preserving norms of science and, second, the potential of governance arrangements which go beyond this ambivalence of case by case MTA contracting by establishing common rules and standards.

The remainder of the article is organised as follows. To begin with, Mertonian norms underpinning the concern are explained in Section 2. Empirical tests for the anticommons hypothesis are presented in Section 3. MTA modes and impacts are studied in Section 4. Anecdotal evidence illustrating MTA effects on research are provided in Section 5. Bibliometric and survey data giving statistical evidence are referred to in Section 6. Finally, concluding remarks are made in Section 7.

2. Theoretical Arguments

Academic scientific behaviour has been characterised by the traditional norms of *communism, universalism, disinterestedness and organised scepticism*.⁹ Residual norms of academic research may even have had some influence on the conduct of industry actors, such as Celera, a joint venture between the Institute for Genomic Research (a private, non-profit genetics laboratory) and Perkin-Elmer (a manufacturer of DNA-sequencing instruments). Celera refrained from claiming certain intellectual property rights in the human genome and publicly released all raw sequence data. Part of the reason for this may be that the value of intellectual property rights in DNA sequence data had been diminished by the public-consortium data release. In addition, the interest of Perkin-Elmer could be well served by having DNA sequence data disseminated widely so the company could create a demand for its sequencing machines.¹⁰

From the beginning of the Cold War, academic science began deviating more and more from this long-established mode. This change was accelerated after the Bayh–Dole Act in the United States in 1980. Most European countries, except for Sweden, mirrored the Bayh–Dole Act to allow universities to become owners of patents for inventions made by their employees according to certain conditions. Moreover, universities have the obligation to give a fair return to inventors through royalties or equity. In this manner, the privatisation of academic science subverted the social order of academia and a post-academic ethos emerged, the counter-Mertonian norms. Ziman (2000) gave the emerging system the name ‘post-academic science’.¹¹ What is changing is the definition of science itself: the new regime shows that the idealised picture of academic science no longer holds. The term ‘post-academic science’ suggests that science now fits neither the academic nor the industrial model. According to Ziman, post-academic science may be characterised as *proprietary, local, authoritarian, commissioned and expert*. As to the link

between contract (i.e. MTA) and (intellectual) property, Posner makes the point that ‘if the only people who have access to your property happen to be the people with whom you have a contract, you can regulate their access by means of contract ...’.¹²

Because of the Bayh–Dole Act and similar regimes elsewhere, technology transfer officers (TTOs) proliferated in universities and research agencies. TTOs, selected by university or agency authorities, are essentially mandated to protect the financial interests of the university or agency, while academics, selected by their peers, are ultimately mandated to push the frontiers of knowledge forward. It is worth noting that these two different visions of what is the *raison d’être* of universities and research agencies have caused tension between the two communities. Sometimes these two missions might conflict; some TTOs complained in the 2007 Annual Meeting of the Association of University Technology Managers (AUTM) that university promotions and tenures are mostly based on publication, which is why professors prefer to publish their research in academic journals rather than as patents.

In this respect, Campbell and Bendauid have investigated the attitudes of TTOs, individuals working for universities and laboratories that manage transfer of information from their employer institution.¹³ The study demonstrated that TTOs are more likely to withhold information until publication, and that TTOs feel scientists should be more careful when sharing information to protect publication interests. Most TTOs work at institutions that do not have policies relating to information sharing. Finally, TTOs think that publication may hurt a university’s commercial interests since the information is dispersed amongst competing researchers and the public at large.

3. Empirical Tests for the Anticommons Hypothesis

As a resource is prone to underuse in a *tragedy of the anticommons*,¹⁴ when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use, it has been suggested that privatisation of upstream biomedical research may create anticommons properties. So far, the anticommons hypothesis has been empirically tested with bibliometric measures and surveys. In a bibliometric approach, Murray and Stern found evidence of a modest anticommons effect.¹⁵ Empirically, it was found that the citation rate after the patent grant declines by between 9% and 17%. This decline becomes more pronounced with the number of years elapsed since the date of the patent grant. In particular, the decline is relevant for articles authored by researchers with public sector affiliations.

The anticommons hypothesis includes patent thickets, patent floods and patent clusters. In the surveys of Thomas *et al.*, concern was expressed about the monopolisation by companies of an entire gene and its mutations for all diagnostic and therapeutic purposes.¹⁶ In the same vein, exclusive rights to several patents have been used to monopolise testing services.¹⁷ There was very rapid adoption of gene testing by laboratories soon after the gene was published and before the patent issuance and enforcement.¹⁸ In genetic tests, patents were unnecessary for rapid translation of the gene discovery into clinical-testing services.¹⁹ In contrast, the survey of Merz *et al.* has shown that patents inhibited adoption, perhaps by creating a financial risk for laboratories and a disincentive to develop and validate clinical assay that could be stopped by patent enforcement.²⁰

Finally, a contrast between the commons, the public domain and patented technologies for research has been made by the literature. In the survey by Hansen *et al.* for members of the American Association for the Advancement of Science, industry involved in biosciences, chemistry, earth sciences, physics, astronomy, engineering, mathematics, computer sciences, social sciences and behavioural sciences, reported higher rates of patented technology acquisitions than academia.²¹ The acquisition of patented technology happened most quickly with non-exclusive licences. The greatest proportion of protracted transactions involved an exclusive licence. Biosciences reported higher rates of patented technology acquisition than other fields and had more protracted negotiations than any other field. Acquisitions of technologies from industry were completed more quickly than those from academia. Industrial biosciences reported delay, change or abandonment of research at the highest rate. Difficulties affecting research have several reasons: overly complex negotiations, high fees or royalties, non-licenseable patents, breakdowns in negotiations, inability to determine the intellectual property status of the technology, notification of an infringement claim and royalty stacking. It seems that academia may have been less affected than industry by more restrictive and formal practices in the acquisition of patented technologies for research.

4. MTA Modes and Impacts

The phrase 'research material' connotes a user perspective rather than a provider perspective because what a user sees as a research tool, a provider may see as a valuable end product for sale to customers.²² MTAs are contracts used to transfer the use of proprietary materials owned by for-profit or not-for-profit organisations. MTAs are not always required when asking for external research material. The negotiations and obligations demanded by an MTA might stifle the broad dissemination of new discoveries, slow down the technology transfer process and limit future avenues of research and product development. Examples of such obligations are: reach-through provisions, royalties and fees, publication restrictions and conflicting obligations with funding bodies.

Significant obstacles to efficient bargaining are likely to be created not only by the patenting of upstream inventions, but also by the restrictive MTAs used by many corporate owners of research material. Because MTAs usually give the provider the right to control its future use, those who are attempting to develop a product that relies on many different research materials may be confronted with inconsistent and overlapping obligations. The use of restrictive MTAs gives each upstream patent owner a continuing right to be present at the bargaining table as a research project moves downstream toward product development.²³

According to Mirowsky and Van Horn, an MTA is a special signal that commercial firms award to academics when they are unenthusiastic about the request to collaborate.²⁴ Furthermore, Streitz and Bennett argue that when companies are material suppliers, academic scientists might be tightly restricted in their academic freedom because MTAs may require researchers to assign or license intellectual property rights to discoveries made in the course of using the material, prohibit sharing research material with other researchers or forbid sending it to other institutions.²⁵ These restraints to academic freedom have thereby generated concerns about limiting the progress of science.

In the United States, to simplify transfers between non-profit research institutions, the National Institutes of Health (NIH) published in 1995 the final version of

the Uniform Biological Material Transfer Agreement (UBMTA) and the Simple Letter Agreement of the Transfer of Non-Proprietary Biological Material. Although there has been no formal agreement on a format when a for-profit entity is providing material to a non-profit organisation, the AUTM, the NIH and industry representatives developed a draft agreement in 1992. It is worth noting that at the 2003 AUTM annual meeting, a special interest group on MTAs (MTA SIG) met for the first time and has been dealing with MTA issues since then. The MTA SIG currently has two working groups, viz.: the e-MTA Commons group, which is working to create a universal, web-based MTA management system; and the Negotiations Issues group, which is actively engaging in finding solutions to common negotiation issues between institutions and industry.

While the terms of the UBMTA require that university signatories transfer biological materials freely to other academic institutions, researchers have complained that a significant number of universities is not following the terms of the UBMTA. There is evidence to suggest that MTAs from universities providing research material to other universities have included clauses, *inter alia*, requiring assignments of intellectual property rights in research results that arise from the use of the research material, publication delays pending a determination of intellectual property rights and prohibitions of transfer of the research material to other research institutions.²⁶

There is a substantial amount that agencies such as the NIH can do to rein in such violators of the sharing norm. For example, in response to concerns that some universities are using MTAs that violate the UBMTA, the NIH has issued a set of principles and guidelines on obtaining and disseminating biomedical research material for recipients of NIH research grants and contracts in 1999. In this way, the NIH assisted funding recipients in determining reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools), and restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intention is to help NIH-funded recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh–Dole Act and NIH funding agreements.²⁷

The experience of the NIH has shown, however, that conditions imposed by patent owners in an MTA can be crafted to ensure both research uses and commercial development. For example, the NIH strategy is to negotiate nonexclusive licences for its internally developed technologies whenever possible. This allows more than one company to develop products using a particular technology, products that may ultimately compete with each other in the marketplace. According to Freire, whenever government funds are used to support a new invention by contractors and grantees, the government has a nonexclusive, royalty-free right to use the patented technology by or on behalf of the government.²⁸ When the research is funded entirely by the private sector, the government has no statutory licence and it is strictly a private matter whether, and under what terms, new intellectual property rights are made available to others for commercial or research purposes.

5. Anecdotal Evidence

The following four cases provide anecdotal evidence of how MTAs have played a role in science by affecting material distribution, liability, disclosure and the

continuation of a research line. First, from 1987 until 1991, Sharon Greenberg was employed as a research assistant on Alzheimer's disease in the Pathology Department of Albert Einstein College of Medicine (AECOM), a division of Yeshiva University. Between 1987 and 1988, Greenberg developed PHF-1, an antibody that can detect specific genetic markers that are associated with Alzheimer's disease, and a cell line that produces PHF-1. The antibody was regarded as promising for aiding the development of a diagnostic test and a treatment for Alzheimer's disease, which could have great commercial value. When Greenberg left the employ of AECOM, she took samples of both PHF-1 and the cell line to her new position in order to continue her work. This was permissible under AECOM policy, which allowed continued academic research by former employees. Furthermore, AECOM would accommodate qualified third parties seeking samples of antibodies and biological materials pursuant to an MTA, which limited use to non-commercial purposes. In June 1994, AECOM learned that Greenberg was distributing PHF-1 and the cell line to various entities, including a commercial entity. When Greenberg asserted that she was the owner of PHF-1 and had the right to distribute it for commercial and academic purposes without interference from AECOM, Yeshiva University commenced its action.²⁹ This case shows that the MTA was envisaged only for academic research. MTAs are contracts that are protected by law. If one of their provisions is not followed, the contract is breached and the wronged party has the right to bring action against the other, such as suing for damages.

Secondly, American Type Culture Collection (ATCC), a non-profit organisation, serves as a long-term repository and distribution centre for living micro-organisms, viruses and cell lines, which it makes available to scientists and researchers around the world. ATCC provides its material through a standard MTA. The MTA also makes the recipient responsible for injuries in connection with the receipt, handling, storage or use of those particular materials.³⁰ This case shows that the MTA foresaw a liability clause. It is usual that an agreement term may require that the recipient indemnify the provider against any damage that may occur through use of the material, implying that the provider is not responsible, even if the material was provided without proper warnings about associated hazards or needed precautions.

A third case involved Sophie Chen, who held the United States patents for PC-Spes and Spes, herbal compositions for treating prostate cancer, and was on the faculty of New York Medical College (NYMC). She and Allan Wang formed International Medical Research (IMR), which manufactured and distributed the dietary supplements at issue. In 1997, Chen, Wang and Leonard Weinglass, who was also an officer of IMR, formed Novaspes, a not-for-profit organisation engaged in cancer research. NYMC entered into a contract characterised as an MTA which required IMR to provide to NYMC the quantity of PC-Spes and its isolated components determined to be necessary for investigating the herbal action against prostate cancer of PC-Spes and its various compounds. The agreement also included a provision prohibiting the recipient from furnishing the materials to any other party without the provider's written consent. Recognising the interest of scientists in disclosing research results through publication in scientific journals, oral presentations and other appropriate means, the agreement also stated:

It is anticipated that IMR researchers will collaborate actively with [NYMC] researchers at every stage of the research process. If [NYMC] or IMR's employees intend to publish any results from the experiments, each will provide the

other party's scientists an opportunity to co-author such publication, if appropriate, under standards accepted within the scientific community.

Ostensibly to protect IMR's interest in complete patent protection, NYMC was required to furnish IMR copies of any proposed publication or presentation at least 45 days before submission.³¹ This case shows that, for academia, the basic restriction was the limitation to publish research results, the restriction to share the material with peers and the obligation of co-authorship upon approval by the provider. The agreement wording allows the provider to determine whether its own confidential information has been improperly disclosed, and whether there are new intellectual rights to be claimed.

A final case involved Washington University (WU) and William Catalona, a scientific authority in prostate cancer. Catalona was employed by WU from July 1976 until February 2003 and he was instrumental in establishing the GU Biorepository for the collection and storage of biological specimens of prostate tissue, blood and DNA samples for prostate cancer research. In 2003, Catalona left his position with WU to take a similar position with Northwestern University and to continue his prostate cancer research. At times, other research institutions have requested and received samples from the GU Biorepository for research projects outside WU or in partnership with WU. The transfer of such material was made pursuant to an MTA. In all MTAs concerning these materials, including those wherein Catalona was the provider, the university clearly exerted its ownership interest without objection by Catalona. When Catalona moved to another university, he tried to take the tissues with him, but WU refused, saying that it owned the tissues; the judge upheld the university's position.³² This case clearly illustrates how research lines can be stopped because university authorities enforce their property rights on research materials. It is worth noting that the research exemption, applicable in certain domains of property, was not successful here.

6. Statistical Evidence

The MTA clauses and their impacts have been assessed in surveys,³³ or by bibliometrics.³⁴ In the survey approach, MTA modes and consequences are reported by the contacted subjects as answers to questionnaires. In the bibliometric approach, direct measures use text data to test hypotheses on MTA impacts.

The survey of Hansen *et al.* shows that in biosciences, chemistry, earth sciences, physics, astronomy, engineering, mathematics, computer sciences, social sciences and behavioural sciences, the greatest overall proportion of research members of the American Association for the Advancement of Science reported acquiring their last patented technology through MTAs and that the use of MTAs was concentrated in academic biosciences.³⁵ It appears that academia may have been less affected than industry by more restrictive and formal practices in the acquisition of patented technologies for research.

According to the survey of academic researchers in biomedicine by Walsh *et al.*, MTAs are positively associated with receiving requested material.³⁶ The findings of a more recent survey by Walsh *et al.*, shown in Table 1, suggest that MTAs are processed largely without incident.³⁷ Nonetheless, even an infrequent problem might have important impacts on scientific and commercial advance if the technology is sufficiently important. For that reason, dedicated measures of impact have been set up in order to test hypotheses.

Table 1. MTA modes

MTA modes	Findings
Exchange formalisation	Prospective industry suppliers are more likely than those from university to ask for an MTA and reach-through rights, royalties and publication restrictions; those asking for a drug are more likely to be presented with an MTA
Contract negotiation	An MTA is not always negotiated. If negotiated, only a minority reported protracted negotiations. Protracted negotiations with industry are more likely to occur than with academia. Requests to industry are more likely to result in a research delay
Professional counselling	The majority of researchers who make the request do not consult their TTOs. If TTOs are involved, the chances of non-compliance or protracted negotiations are higher. Professional counselling is more likely to occur if the request is made to industry, or if the proposed MTA includes royalties, reach-through rights or publication restrictions
Material access	Patented materials, if accompanied by an MTA, are more likely to be supplied than unpatented or non-MTA materials. MTA publication restrictions and demand for royalties are likely to reduce the chances of receiving the material, while co-authorship requests and reach-through provisions do not have a significant independent effect. Co-authorship requests by industry or academia cannot be significantly distinguished
Financial cost	Fees requested by industry or academia for material transfers are rare

Source: Walsh *et al.*, 2007, *op. cit.*

Dedicated measures have been used by Mowery and Ziedonis for the life sciences,³⁸ and by Rodriguez *et al.* for biotechnology in order to test MTA impacts on commercial endeavour and scientific research, respectively.³⁹ Table 2 shows the empirics, findings and discussions of such approaches. The empirical findings may suggest that MTAs did not have a detrimental effect on research and commercial endeavour at universities.

7. Concluding Remarks

To understand how MTAs have affected academic science and to decide what should be done about them, empirical studies have examined them in the context of the Mertonian underpinnings of the anticommons threat. When MTAs were first developed, there was a fear that privatised research practices in academia would undermine the progress of research. Such is the background of the scholarly studies reviewed here. Since the Bayh–Dole Act, the anticommons threat has had a strange career. At first, it was simply declared, apparently in the profound belief that anecdotal evidence would suffice to accept the anticommons hypothesis.

The turning point in testing the effects of MTAs on scientific research and commercial endeavour was marked by statistical studies based on surveys and bibliometric measures. These two types of empirical studies have given answers to the basic questions that had gone unasked since academia was threatened by different modes of doing science (from Merton to Ziman's modes). In particular, bibliometric approaches have marked a radical departure, not only from reliance on anecdotal evidence, but also from the attitudinal approach of surveys.

The review of the statistical evidence shows that the concern as to whether MTAs affect the progress of science has been translated into testable hypotheses. These studies suggest that MTAs were not affecting scientific research or commercial endeavour in such a way as to impede the progress of science of cumulative

Table 2. MTA impact on scientific research and commercial endeavour

MTA impact	Empirics	Findings	Discussions
Commercial endeavour	MTAs, patenting, citing and licensing patterns	MTA-related disclosures are more likely to be patented than those not related to MTAs. Patents associated with MTA-related disclosures are cited more intensively than patents unrelated to MTAs. MTAs are not a significant impediment to rapid citation of associated patents by other inventors. MTA-related patents are more licensed than patents not linked to MTAs	MTAs and patents might be complements rather than substitutes. MTAs might not raise barriers to commercial exploitation of knowledge embodied in invention disclosures. MTAs do not seem to impede the licensing of patents linked to them
Scientific research	MTAs and research agendas	There is an overlap of research agendas between MTAs and non-MTA users	The cognitive linkages suggest that MTAs might not be affecting research agenda-setting in industry, government and academia
	MTAs and co-publication activity	The pattern of academic nodes that used MTAs was more stable than that of industry, where entrances and departures occurred more often. The pattern of nodes that did not use MTAs in their collaborative publications was erratic	The expansion rate of collaboration and new collaboration in publications, whether using MTAs or not, outpaced the entry of nodes, suggesting a more connected field or a denser network. MTAs might not have interfered in such a way to limit co-publication activity of research organisations in the network
	MTAs and visibility of researchers	Researchers who used MTAs were more visible than those who did not, controlling for seniority and co-authorship	Being a user of MTAs might be a reflection of systematic differences in the stratification of science in terms of visibility

Source: Mowery and Ziedonis, *op. cit.*; Rodriguez *et al.*, 2007a, 2007b, 2008, *op. cit.*

innovation. These findings have prompted the most likely explanation that science itself adapted to the commercialisation means of Ziman's norms. These statistical studies have thus made progress in the understanding of the mode and impact, but such implications need to integrate diverse results from anecdotal evidence that are currently considered separately.

Apart from MTA solutions at national level based on anecdotal evidence, the international community has developed initiatives to standardise the sharing of biological material. As a result of the International Treaty on Plant Genetic Resources for Food and Agriculture in 2001, a Standard MTA has been available since 2006 for the Multilateral System under the auspices of the Food and Agriculture Organisation. In addition, the Parties of the Convention on Biological Diversity are engaged in the negotiation of an international regime on access and benefit sharing (ABS) based on a recommendation adopted at the World Summit on Sustainable Development in 2002. The international community adopted the Bonn Guidelines as a voluntary framework of ABS at the national level in 2002. The Parties mandated a Working Group on ABS to negotiate the international regime in close co-operation with the Working Group on Traditional Knowledge in 2004.

The negotiation will be finalised at the tenth meeting of the Conference of the Parties in October 2010. Finally, the World Health Organisation has been working on the standardisation of the sharing of the pandemic flu virus since 2007 and two intergovernmental meetings have been held so far.

Notes and References

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