The roles of Material Transfer Agreements
in genetics databases and Bio-banks

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1. Introduction

Biobanks are an emerging, yet fast developing phenomenon in the field of genomic and proteonomic research[1]. As in every field characterized by a rapid growth of

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[1] A Biobank can be generally defined as a storage facility of biological and genetic material that will be used for study, development of research and experiments. Biobanks are usually maintained by public or

(commercial) interests, the legal and contractual aspects are gaining momentum. The exchange of biological and research materials is becoming more and more formalized, and – differently from a few years ago – providing institutions now tend to impose the use of specific contract forms that detail the rights and obligations attached to the material. Such contractual agreements are commonly referred to as "Material Transfer Agreements", or MTAs.

In the origins of biobanks and of genetic research more generally, the exchange of bio-material was "free", or at least "informal". Such situation is common to many avant-garde fields during their generative period, which usually unfolds within the boundaries of public or academic research. Historically, academics and public scientists disseminated their research findings and results through free and open channels such as informal sharing, journal publications, or presentations at conferences and seminars. In many instances, those basic discoveries had little direct commercial value and only occasionally were deemed worthy enough to try the patenting option. However, the same discoveries quite often proved highly useful for other researchers to elaborate upon[2]. The disclosure, i.e. making the findings public, was the main rewarding scheme[3]. "The reward structure of academic science reinforced that practice, awarding prestige and tenure on the basis of discoveries published in journals and provided openly to the scientific community"[4].

As said, though, this is history. The evolution of the sector has more recently taken a different path. Reasons are many – mostly market and industry-driven. Nonetheless, the law has also played a role in this shift[5]. New legislation has substantially

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private research institutions, such as universities, hospitals, medical or pharmaceutical companies. Biobanks do not conserve exclusively the material but also a great deal of informations, such as the clinical information relevant to a specific biological sample. Biobanks are huge databases of samples and informations that raise a great deal of legal issues ranging from privacy to intellectual property, and contracts.

2 See Hansen et al. 2005, p. 5.

3 Thus excluding some of the Intellectual Property tools here recalled, such as trade secrets. A trade secret is protected as long as it remains secret, which contrasts with the necessity to publish the results. Patents, when allowed, also are a tool whose real utility needs to be tested in relation to the scientific sector, the funding/employing entity and the business method pursued. Delays in publishing connected to the patent application, and costs, sometimes represent a barrier in a sector where the reward is based on a "publish-or-perish" base.

4 See Hansen et al. 2005, p. 5.

5 See Caso R., (Ed.) Ricerca scientifica pubblica, trasferimento tecnologico e proprietà intellettuale,Bologna, 2005.

influenced the funding system of public research centres such as Universities[6], and courts have judicially sanctioned the patentability of biological products and organisms[7].

In order to speculate about a possible evolutionary legal scenario in the biotech field, we can try to analogize from another field, which is also based on new technologies, but has already achieved maturity. Let us turn our attention to the origin of the computing industry.

At the beginning, software was just a by-product of what, at that time, was the real core of the computing industry: hardware. Hardware was the added value, and the software was just some additional information that was important, but not essential. It had the same importance as manuals and documentation. At that time (the 1960s and 70s) one big company, IBM, was dominating this field, and was based mainly on the production of huge computers, square meters in dimension, for the simultaneous processing of many thousands of calculations. It is interesting to note how, during this time, most hardware was not sold, but rented. Software had no autonomous value at all, also because it was strictly hardware-dependant. A given piece of software would have not run on a different computer. Hardware was not standardized and every machine was almost unique, especially at the beginning. However, with the pass of time, hardware got cheaper, electronic engineering and programming were taught at universities, computers got smaller and more standardized. Software became more sophisticated and could be exported to different hardware that were compliant with a specific design[8].

The idea of Personal Computers (PCs) arose, meaning computers that could be

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6 See for example the Bayh-Dole Act, U.S.C. Title 35, Part 2, Chapter 18, § 200 "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; […] to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; […] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area ".

7 The first case affirming patentability in this field is Sidney A. Diamond, Commissioner of Patents and Trademarks, v. Ananda M. Chakrabarty, et al., 447 U.S. 303 100 S. Ct. 2204, 65 L. Ed. 2d 144, 206 U.S.P.Q. 193; subsequently many other cases have build upon this. Affirming patentability of purified substances that are naturally occurring, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).

8 Among the many studies that have analyzed this period of technological evolution, of particular interest is Zittrain 2008.

owned by smaller labs or even individuals. IBM did not understand such shift, but Microsoft (yet to be incorporated) did. Microsoft business was, and is, based on "software as a product". What had been the rule thus far, when software was a niche research area of a few visionary researchers, changed drastically. The possibility to exchange lines of software code in source form without having to get the approval of a legal department, or a software licence signed, slowly but inexorably disappeared.

The enforcement of technical and legal protections for software has been strong: binary distribution, trade secret protection, copyright protection, copyright expansion and the related Public Domain erosion, the still contentious patentability, Digital Rights Management (DRM) and Technological Protection Measures (TPM) and so on[9]. As a response, a counter-movement has emerged: Free Libre Open Source Software (FLOSS). Contrasting the technical, legal and contractual "closure" of the mainstream computing industry, FLOSS ethical and business methods are based on access to the source code and the freedoms to run, study, modify and redistribute the software[10].

In the field of biotechnologies and the exchange of bio-samples and bio-materials is happening something similar to the brief summary of 40 years of history of computer science just told. It is too early to say whether exactly the same evolution will happen, being the biobank market still in its emerging phase. However, it is evident the parallels between the 21st century biomolecular researcher that sends a line of cells to his fellow at another institution, to that of the 20th century computer scientist who sent a line of code to another colleague conducting a complementary experiment. In both cases, at the beginning of the story, when cell lines or code lines were commercial-less cutting-edge experiments, sharing and free exchange were the default. Not just because there was no commercial interest involved, but also because it was the quickest and most efficient way to evolve in such field: collaboration. With the advent of industries and markets strongly based on such innovations, it is natural that companies and incorporations become interested in gaining total control over the future patterns of their own financial investments. Whether it is not under debate that such strategic behaviour is central for companies engaged in a so competitive market such that of new technologies, the same

9 See Perry 2005, Id. 2000; Caso 2004; Rossato 2006; Perry and Margoni 2010.

10 See http://en.wikipedia.org/wiki/The_Free_Software_Definition.

does not necessarily hold true for the technological evolution per se.

In this paper, starting from the reported analogy, we will analyse the role (or better the role*s*) that a specific document, the Material Transfer Agreement (MTA), has accrued in the exchange of bio-materials between research institutions. We will see how fundamental such documents have become in the most recent years, and that an uncontrolled proliferation of them could bring about a highly inefficient market situation. We will further see how standardization will partially fix the problems connected to the exchange of bio-materials and bio-samples. However, whilst standardization possesses undeniable advantages, it has to cope with a minimum level of flexibility, otherwise it will not be able to catch the huge varieties of situations involved. We will finally observe, how new digital and web-based collaborative efforts can contribute to achieve such trade-off between standardization and flexibility.

2 Definitions

Material Transfer Agreements (MTAs), are legal agreements governing the transfer of research materials and tools between universities, public and private research centres and the government. The kinds of clauses contained in such MTAs – whether they assign the property of the biological material or only offer a temporary right to use such material, and the connected limitations and conditions – will be analysed further ahead in this paper. At this stage, it suffices to our definition the aforementioned: the MTAs is the document accompanying the bio-material where we can find all the legal provisions that bind our giving or receiving the material, and the use we can do with it.

Regarding the object of such agreement, i.e., what we called so far bio-material or bio-tools, or again research material, it represents a huge and heterogeneous category, comprising cell lines, DNA segments, isolated and purified DNA, bacterial cultures, nucleotides, proteins, plasmids, archeas, antibodies, transgenic organisms, pharmaceuticals, chemicals, know-how, and many other similar products, that are

developed by a given research infrastructure. It is worth noting that such a variegate category is composed by elements that may be protected by different legal tools, such as patents, trade-secret or confidential information, copyright, database rights, privacy, a sum of all/some of the above, or none. It is self-evident that given a specific MTA, its validity or enforceability, may be influenced, some times strongly, by the fact that the object of the agreement is protected or not by the legal tools above briefly mentioned.

3. Why Exchange?

At this point one might question why to exchange those materials. If they are so valuable, as reflected by their growing commercial value, why an entity should be interested in exchanging them, rather than in keeping as its best protected secret?

The reasons are many and vary following the nature of the entity, the nature of the object, and the nature of the market or industry. It is a common sense to affirm that to reinvent what has been already invented is at best a waste of time. More technically, to double the monetary, temporal, and human investment, in order to re-implement what already exists, is a clear system inefficiency. While such situation might be a legitimate consequence of specific business decisions, it is hardly conceivable under a pure scientific standpoint.

A balanced evaluation of such situation strongly depends on the type of business and funding models of the involved players. We have seen that one of the multiple players involved in the exchange of material are public research entities: in such case the protection of the financial investments plays a more modest role. Public research institutions and universities are usually committed to pursue scientific objectives that do not necessarily have to create immediate financial revenues. This is not to affirm that such entities are not compelled by a trade-off between their institutional goal (research) and their economic budget and cash flow. However, the goal of such entities is not to pay a dividend to their shareholders, rather to achieve public policy objectives. The difference in role and in funding is confirmed by the average delay time in providing bio-samples

which is significantly lower in cases of public bodies[11].

Regarding the nature of the object, it is a glaringly different scenario that of a final bio-product from that of a research tool. In the former case, in fact, it would be inconsiderate to share a potentially successful product with direct marketability, with a potential competitor's laboratory. Even accompanied by the most restrictive MTA, such sharing would make little sense for the providing laboratory. In contrast, in the case of the research tool, the situation can be close to the opposite: the research tool main objective is to help and assist in the research phase and this is its market function. The final product is completely irrelevant, the research tools is just that, a tool, an instrument that helps the activity of research. In such case, it would be much more likely that the contacted lab will send the research tool, which will be accompanied by an adequate MTA, establishing what can be done with it and what not, and the conditions.

Finally, also the relevant market or industry may make a difference in the willingness or ease with which a given lab will share its bio-assets. Some markets or industries are extremely competitive and the research that they develop has a direct or almost direct applicability to a given marketable product. Chemicals and pharmaceuticals are examples of such category. On the other side, we may have labs that develop their activities in basic research, where the direct marketability of a product is usually remote. In those cases, though, the fame and quality of a given result are powerful tools to attract funding and prestige to a specific lab. In the latter case, once again, it will be more likely to obtain the required material.

4 The function of MTAs

We have already pointed out the variegate status under which a given bio-sample could be protected. Almost all the legal tools offered by the broad category of Intellectual Property – e.g., patents, copyright, trade-secret, confidentiality, databases – plus some

[11] See Campbell et al. 2002, p. 473; Dove 2002, p. 425; Hansen et al. 2005; Baca 2006; Walsh et. al. 2007, and *infra* in this article.

others such as privacy and data protection, are potentially involved.

For any of the aforementioned situations the "default rules" are different, that is to say, what can be done and what cannot be done with a given bio-material will very significantly whether it is protected by, say, copyright or patents. If we consider that the legal tools are not only the two just mentioned (copyright and patents) but all those identified above, and in many cases the same material has the potentiality to be protected by more than only one legal tool, we see how many combinations we can obtain. Such a situation, that can be iconoclastically seen as a legal minefield, is serious enough as to stifle scientific development, by stopping sharing and collaborations between labs, between private and the public sectors, and finally between scientists in general.

Given the depicted scenario, the utmost importance that a well structured MTA can achieve becomes manifest. In particular MTAs can be said to fulfill the following main tasks:

- To set out the boundaries for how the material is to be used;
- To determine the relationship between the parties involved in the transfer of the material;
- To offer greater levels of certainty that the use of the materials is within the use originally contemplated;
- To contribute avoiding those liabilities arising from misuse of the material;
- To help preserving intellectual property and attribution rights;

Additionally, MTAs are eligible for indicating another set of more "complex" rules, such as the so called *reach-through*, *grant-back*, or *co-authoring* clauses. However, the legal enforceability of the latter set of clauses is particularly debated, depending on the relevant legal system, as they may violate rules on contract formation, consumer-protection, anti-competitive behaviours, and moral rights.

5 The intrinsic limits of MTAs.

The main limit of an MTA is rooted in its very nature, that to be a private ordering tool[12]. In other words, for an MTA to be successfully implemented it is necessary that the two (or more) parties agree on the (sometimes quite complex) content. To say this, is to transfer the problem to a different layer, which is functionally superordinate to the conclusion of a the MTA: the negotiation. During such phase the parties (or more often their legal departments) exchange offer and acceptance to reach a common agreement on the many different aspects connected with the transfer of the material.

At this stage, we can observe a first major issue with MTAs: what the legal department is pursuing, sometime does not correspond to the needs of the involved researchers. Here, we have the opportunity to observe clearly the dichotomy between the scientific roots and the financial ones of the bio-medical research. On the one side, in fact, the legal department is trying to protect the legal assets of the (public or private) institution, while on the other one, the researchers are trying to achieve new results and solutions. A good communication between the involved researchers and the legal representatives (and a common vocabulary and background to the two) is essential in order to achieve a good document that protects adequately both the assets of the entity and the interest of scientific evolution.

In light of what set out above, it could be inferred that a well written MTA, that represents adequately and clearly both entrepreneurial and scientific interest, is the solution to all, or at least many, of the problems connected with the transfer of bio-materials among labs and research bodies. Unfortunately, things, as usual, are not that straightforward, and as much as any other tool, also contracts, are just a tool, and its ultimate success depends on how it is used and implemented.

The scenario where, upon the necessity of a cell line that is known to be developed by another research lab, it suffices to ask for it, sign the MTA, and to obtain the material without further delay, is too many times unrealistic. Much more common in the real practice are situations where your colleague declares to be happy to send you a

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12 See Elkin-Koren 2005.

reagent fundamental for some experiment you are conducting, however it is not in his power to offer the final authorization. Nevertheless, you can have your university to sign an MTA, by contacting her legal department. Usually, when the MTA negotiations are finally concluded, the field season is over, your grant has expired turning the experiment, and consequently the reagent you have finally obtained, completely useless, and what is worse, you wasted a lot of time with no results.

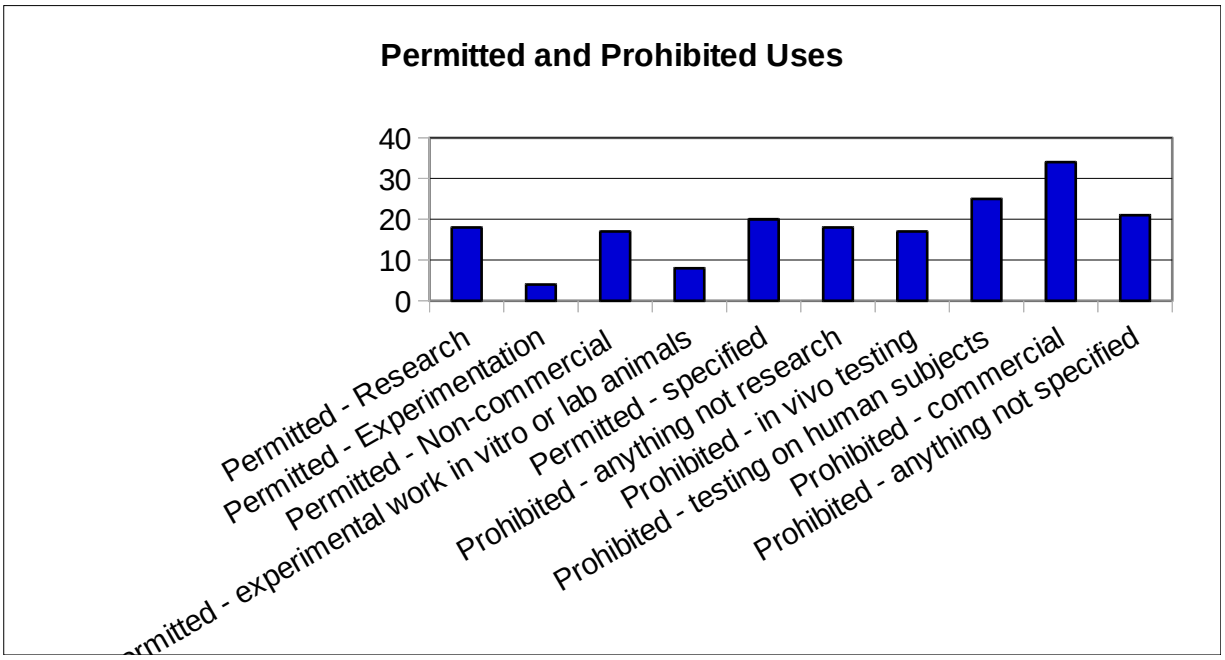
In the biological and biomedical fields, as much as, or even more than, in any other field, timely responses to requests are fundamentals. To obtain the material you need, six months after your request, usually turns your experiment completely irrelevant, creates a huge waste of time for yourself and your colleagues, and causes discredit to you and your research, since most likely you have not been producing any result during the past semester.

Access to research material is also, and many times, mainly, a matter of reducing *transaction costs*. By transaction cost we refer to those non-monetary (but monetarizable) costs related to:

- Time (how long does it take from the request to the eventual reception of the requested);
- Contracts negotiations (personnel, legal representatives, communications from/to legal and scientific departments);
- Rights negotiated (clear understanding of the commercial and business consequences of the transfer or reservation of specific rights);
- Information (how well informed and cross-educated are the subjects involved in the legal negotiations of biological and genetic materials);
- Compatibility (many times the requested/offering lab's material is under some further contractual limitation, originating from precedent negotiations, which turn your request not processable, beyond and regardless of the willingness of the contacted lab)[13].

13 See Walsh et al. 2007.

Figure 1 – Type of uses contemplated by MTAs[14]



According to the aforementioned, different studies have been conducted confirming that delays are a major problem in this environment. Almost one out of two researchers has experienced delays when requesting material from another lab[15]. The reported average waiting time was 4 month when the request was directed to Universities or other public research bodies, and of 6 months when directed to the private sector[16]. However, when delays to the reported waiting time occurred, such delays accrued 8.7 months[17]. Impressive is also the rate of unfulfilled requests, that is 12% when directed to public institutions, and 33% when directed to private ones[18].

The reported situation is variegate, and differently affected by waiting times and delays depending on the specific field, country, market, product, and other specificities. It

14 Perry and Krishna 2007.

15 Lei et al. 2009.

16 Id. Walsh reports an average delay of 1 to 2 months, see Walsh et al. 2007.

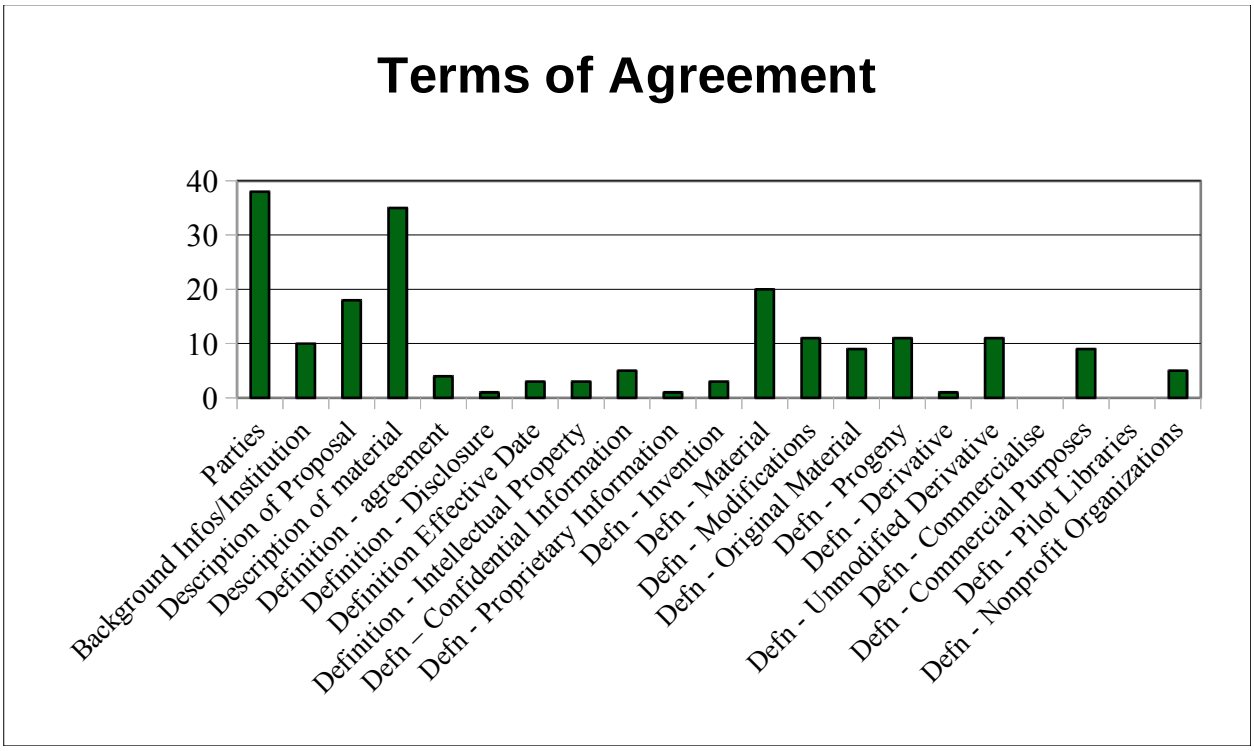
17 See Lei 2009, p. 36.

18 See Walsh reports an average delay of 1 to 2 months, see Walsh et al. 2007.

is, nonetheless, characterized by a common aspect: the extremely high amount of time required to obtain materials necessary for experiments. Delays are related to the increasing complexity of the terms that are negotiated in the MTAs.

A survey conducted by interviewing Canadian private and public research centres that declare to use on a regular bases for their transfers MTAs, shows some of the most common prohibitions and permissions to the research to be conducted with the material, under the form of contractual clauses[19]. Of particular interest is the high variance if we compare the different clauses, which causes a huge heterogeneity among the MTAs used, with the well known compatibility issues (see Figure 1). The same study, also reports extremely high levels of indetermination regarding the temporal horizon of such agreements, where more than 80% do not state it, or leave it for future determinations[20].

Figure 2 – Most common terms in MTAs in Canada[21]



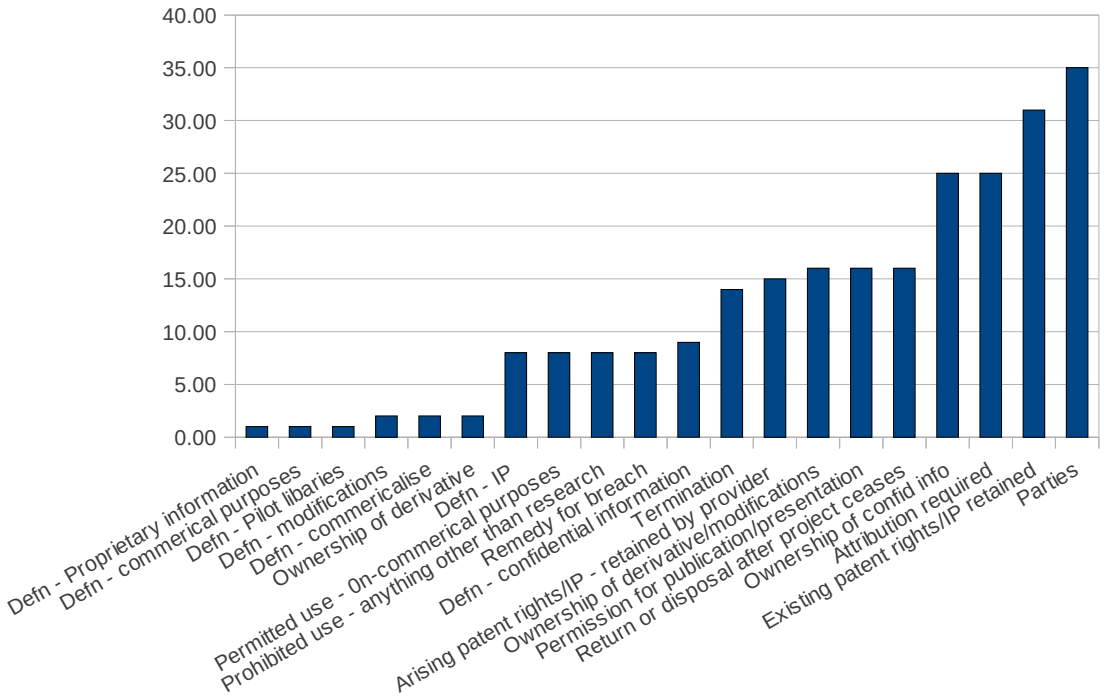
19 Perry and Krishna 2007.

20 Id.

21 Perry and Krishna 2007.

An incredibly high variance is observable also if we compare the presence/absence of the most common terms/definition usually found in MTAs. In fact, whether it is commonly present an adequate definition regarding the identity of the parties and the identification of the material object of transaction, all the other definitions are only partially implemented (see Figure 2). The latter category, can be further subdivided in two: technical definitions and legal definitions. Technical definitions such as: modifications, progeny, original material, unmodified derivative, commercial purposes, are defined in between the 16 and 24 percent of the cases. Legal definitions such as: agreement, disclosure, effective date, intellectual property, confidential information, invention, do not achieve the 10% of the MTAs where are clearly defined (see Figure 3).

Fig. 3 – Most common terms in MTAs in Australia[22]



[22] Perry et al. 2006.

It is apparent how the so far depicted situation is extremely far from the ideal solution where transaction costs are reduced to the minimum, and contractual clauses, relating either to technical or to legal concepts, are clearly defined. In fact, what the data shows, is an extremely poorly harmonized situation, where besides the most basics elements of the agreement (such as the identification of the parties, of the material object of transaction, and of the main usages) all the remaining aspects are only occasionally identified and determined. This is particularly true for legal concepts that in this field are of utmost importance (intellectual property, confidential information, effective date, duration). The most immediate consequence of this environment is an extremely litigious situation, which causes extra (legal) costs and lost of time, in the short period, and a general dis-incentive to enter into agreements in the long period. A lose-lose situation.

6 Is standardization the solution?

A partial solution to such scenario has been proposed with some success some time ago. The outlined problems are not entirely specific to the genetic field, and can be observed more generally in every environment where contractual negotiations are coupled with a particularly competitive and aggressive market. Add to this the absolute novelty of such business sector, and the related lack of commercial customs and standardized clauses, and the picture is complete.

The answer both in the more general contractual field, and in the more specific one here analyzed, carries the same label: standardization. The phenomena of standard form contracts is a well known one to legal theorists and practitioners, and many commentators have written well structured analysis, setting out pros and cons of such phenomenon[23].

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[23] Among the massive literature on this matter, in English language, see: Prausnitz O., The Standardization of Commercial Contracts in English and Continental Law (Sweet and Maxwell 1937); W. David Slawson, The New Meaning of Contract: The Transformation of Contracts Law by Standard Forms, 46 U Pitt L Rev 21, 23 (1984); Richard A. Posner, Economic Analysis of Law § 4.8 at 116 (Aspen 6th ed 2003) ; Katz A., Standard Form Contracts, in Peter Newman, ed, 3 The New Palgrave Dictionary of Economics and the Law 502, 502 (Macmillan 1998); Slawson D., Standard Form Contracts and Democratic Control of Lawmaking Power, 84 Harv L Rev 529, 529 (1971).

The Uniform Biological Material Transfer Agreement has been drafted and set out 16 years ago, in 1995[24], by a joint effort of Autm and National Institute of Health[25]. Such standard contract form template, trimmed around the idiosyncrasies of biological and genetic material transfers, represents still nowadays a very well written piece of document. Such intrinsic quality is reflected in its initial success and diffusion.

As it is possible to read on the *UBMTA Federal Register Materials* the background reasons that brought to the creation of the UBMTA are related to the importance that the National Institutes of Health (NIH) and the Public Health Service (PHS[26]), recognize to the fact that "open access to the results of federally-funded research is a cornerstone of PHS's research policy. In the case of many research projects, this includes not only access to information provided through publications, but also access to biological research materials necessary to replicate or build on the initial results. *Frequently, the exchange of research materials between scientists in separate organizations involves case-by-case negotiation of material transfer agreements* [emphasis added]"[27].

The PHS vision regarding a standard agreement for generalized usage is concerned with addressing the most contentious contractual obligations stated by MTAs and with simplifying the process of sharing biological materials among public and non-profit organizations such as Universities and public research bodies. "The consistent use of the UBMTA by public and non-profit organizations could reduce the administrative burden of sharing materials as investigators come to rely on common acceptance of its terms by cooperating organizations". The PHS finally recognizes that if used for the majority of transfers, the UBMTA could set standards for materials sharing that would be

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24 The Association of University Technology Managers (AUTM), is an association founded in 1974, and "provides professional development and networking opportunities for technology transfer professionals at all career levels and from established and newly forming organizations worldwide", it is currently composed by more than 350 members such as universities, research institutions, teaching hospitals and government agencies as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research, see http://www.autm.net.

25 The National Institute of Health (NIH), is a part of the U.S. Department of Health and Human Services, and is the "nation's medical research agency, making important medical discoveries that improve health and save lives", see http://nih.gov/.

26 The Public Health Service (U.S.) was created by the Public Health Service Act, 1944 with the mission to "protect, promote, and advance the health and safety of the United States", see http://www.usphs.gov/.

27 See Uniform Biological Material Transfer Agreement 1995.

of long-term benefit to the research enterprise and to the public health.

The practical functioning of the UBMTA is also deserving a mention. In fact, in order to simplify and reduce even further the cost connected with negotiations between parties, the UBMTA should be approved at the organizational level, and handled in a master agreement or treaty format, so that "individual transfers could be made with reference to the UBMTA, without the need for separate negotiation of an individual document to cover each transfer". As a result, transfers of biological materials would be accomplished by an Implementing Letter containing a description of the material and a statement indicating that "the material was being transferred in accordance with the terms of the UBMTA [...] Thus, sharing of materials between organizations, each of which had executed the UBMTA, would be significantly simplified. At the same time, any organization would retain the option to handle specific material with unusual commercial or research value on a customized basis. Thus, the use of the UBMTA would not be mandatory, even for signatory organizations"[28]. Currently, there are 420 research institutions that have signed the Master UBMTA Agreement[29].

The efforts produced toward the creation of a uniform agreement have also contributed to fix some of the issues, that at the time of the drafting process, were felt as particularly compelling by the scientific community, industrial players and technological transfer departments. In fact, before the final version, the NIH published a draft prepared by PHS and invited public comments. Thanks to this crowd-sourced public debate, some taxonomic aspects have found a precise definition, in particular:

- Modifications. Such term is common in MTAs however, is usually poorly defined if at all. The UBMTA defines precisely that modifications are developed by the recipients and contain or incorporates the material as given by the provider.
- Profit – non-profit organizations. Another common distinction in many MTAs regards the financial/institutional goal, although, once again, without a widely accepted definition of the concept. The UBMTA implements the definition as codified by the the

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[28] Id. at 12771 – 12772.

[29] See Signatories to the March 8, 1995, Master UBMTA Agreement, of the Association of University Technology Managers (AUTM), available at: http://www.autm.net/AM/Template.cfm?Section=Technology_Transfer_Resources&Template=/CM/ContentDisplay.cfm&ContentID=4636. Accessed 15 January 2011.

Bayh-Dole Act[30].

- Substances other than modification, progeny, or unmodified derivatives. The UBMTA clarifies that any other substance created by the recipient through the use of the material which are not modifications, progeny or unmodified derivatives of material are owned by the recipient, who is free to license them without any interference by the provider of the material.
- Reach-through. This types of clauses are sometimes present in a variety of MTAs, and usually refer to the claim of property rights on the results obtained by the recipient. The UBMTA does not provide for any type of "reach-through" rights for the provider of the Material, i.e., it does not claim any property right in products developed by the recipient through the use of the transferred material.

This brief overview points out some of the positive aspects of the UBMTA. However, throwing and eye on the past 15 years, we can undoubtedly say that its overall usage and application – after its initial success – has been rather limited, and many research universities have drafted their own MTAs[31]. Let us spend a few words on why a good document has proved not as successful as it should have.

The main problem connected to the UBMTA is to be *monolithic*. In fact, as it is usual for standard contract forms, the UBMTA was and still is a "take-it-or-leave-it" tool. It fixes the problem connected with endless negotiations and human and capital resources overhead, by turning the whole regulatory framework of such MTA into an invariant set of clauses. This represents a very effective way to fix one of the main problems we have seen in connection to MTA negotiations. However, the solution is so drastic that sometimes is worse than the problem. So much standardization created a monolithic body that has lost the ability to adapt and catch all the tiny, but many times significant, differences that the biotechnological environment possesses.

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30 35 U.S.C. 18(201)(i) states: "(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501 (c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501 (a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute".

31 See in the same direction, among others, Rai and Eisenberg 2004.

Further, it is also worth noting that the UBMTA has been geared exclusively to a University-to-University relationship, and whether nothing impedes that a commercial or for-profit entity decides to use it, the private sector does not represent its natural playground.

Another type of bias is connected with the legal nature of such tool. Standard form contracts suffer from many other flaws that the legal theory has successively identified and that can be briefly summarized as follows:

- Knowledge of content. Many times the contract is not negotiated by the parties, but one party submit a pre-compiled form to the other who is left with the only choice to adhere to it or not. Precisely for such reason, the latter does not read (carefully enough) all the clauses that is going to accept. Such type of strong standardization represents an incentive to a "blind" acceptance of the contract, that favours future litigations. Another name for standard form contracts is "adhesion contracts".
- Complete disclosure of the terms of the agreement. Such problem might be less relevant in the case of the UBMTA, since even when the recipient of the material only receives the implementing letter – that makes reference to the Master UBMTA – the signatories institutions have a legal obligation to adhere strictly to the terms of the UBMTA. However, such scheme, where the institutions are signatories of a master document, and scientists only of an implementing letter, can contribute to worsen the awareness of what one of the two parties, usually the recipient, is obliged to, or prohibited from do(ing). This situation is a clear contribution to unconscious contract non-compliances.
- Since clauses are given for a plurality of situations, especially in cross-jurisdiction bargaining, there are chances that some of the provisions will be deemed unenforceable by the relevant court of justice. Such problem are usually fixed by the insertion of a choice of jurisdiction or/and venue clause, however, once again, this represents a typical situation where the stronger party can impose particularly burdensome obligations to the weaker party.
- Conform behaviour. If a standard form contract is the default in a given environment, it becomes less likely that a party, even when is not completely convinced

of the content, will decide not to sign the contract. In a non-legal environment, it might become even more hard to justify a non-conform contractual orientation. Sometime, in our specific case, the necessity to have the material right away, will contribute to post-pone the worries connected to one or more clauses, which might be of only eventual application ("should you obtain a patent using our material …"), but could indeed bring about an undesirable situation (" … you are obliged to name us co-authors").

- Finally, the inequality of the power of the parties involved. Usually, in fact, one of the two parties has less contractual power (less money, less human resources, informational deficits, etc), which adds up to the urgency for such party to obtain the material, creating an undue burden on the already weaker party. While it is true that in the case of the UBMTA such situation is less likely thanks to the inherent balance of the document, this aspect still represents a major legal and doctrinal issue for the category of standard form contracts.

7 Can technology help improve such situation?

If we agree with Walsh[32] we acknowledge that one of the major issues connected with the transfer of bio-samples is related to its prompt availability and circulation among labs. We should also remember that delays are caused much more often than expected by transaction costs (time, informational deficits, human resources) rather than by Intellectual Property rights, which may or may not attach to the object of transactions.

In light of that, the goal of the UBMTA – reduction of transaction costs – could be pursued through a different path, one that offers a certain level of standardization, without imposing a too strong rigidity. Such solution takes the name of *digital and web-based technologies*.

32 See Walsh et al. 2007.

7.1 Metadata-driven approach

The following 932 characters of code can efficiently contribute to fix the problem:

<div xmlns:cc="http://creativecommons.org/ns#"
xmlns:sc="http://sciencecommons.org/ns#" xmlns:dc="http://purl.org/dc/elements/1.1/">
The material is available from <a
rel="sc:provider" href=""> under the following offers:

<a rel='sc:agreement' href='agreements/sc-rp/1.0?
source=mta&fieldSpec=aaa&endDate=04/06/10&transmittalFee=1&legalURL=agreeme
nts/sc-rp/1.0/legalcode'>Science Commons MTA.

The offer expires on <span proper/media/ECCB-
8A44/Logo_lawtech.jpgty="sc:expires">04/06/10
The transmittal fee is
1
The offer is available to <span
property="sc:recipientType">nonProfit institutions
<span rel="cc:prohbits"
class="sc:ProtocolProhibition">Offer is limited to use with protocol <span
property="sc:protocol">aaa

Such code is a *metadata*, that is, a piece of code that can be appended to the digital representation of the material that a provider or a receiver is interested in either offering or using. The enormous advantage of such implementation is connected with the web-based infrastructure that this scheme enables. A metadata-driven approach is a methodology that can be implemented by many different players and projects in different ways. In this paper we use as a reference example one of this projects, probably the most developed in this area, that is characterized by an open and public work-flow, and by a deep understanding not only of the biological and scientific part of the problem, but also of the legal and technological one. Such project is called Science Commons[33], and was

33 See http://sciencecommons.org/projects/licensing/.

born as a particular application in the field of science, of its "older brother", the more famous Creative Commons[34]. To recall such connection is fundamental, as the methodological approach (openness, web-based, modularity, and representation in human, legal and machine code of the contractual terms), has been borrowed from the latter. The Science Commons (SC) project also recognizes the validity of the UBMTA, and in fact implements also a version of it, to which it has added the metadata and the commons-deed forms of representation[35].

7.2 Science Commons

The Science Commons MTA project originates from the necessity of reducing the costs associated with the transfer of material, as they have identified – through their own surveys and data[36] – the same results that we have already seen in this study[37]. A metadata and web-based approach, though, is not only helpful with regard to the understanding of the contractual terms. It possesses also the capability of facilitating the identification and location of the material that a scientist or a lab is seeking, reducing the amount of time (usually weeks or even months) to the time of a web-based inquiry. The metadata-driven approach allows for an easy integration into search engines, as well as into literature databases so that "scientists can 'one-click' in-line as they perform typical research". Such web-based infrastructure further allows for tracking materials propagation and reuse, "creating new data points for the impact of scientific research that are more dimensional than simple citation indexes, tying specific materials to related peer-reviewed articles and data sets[38]", through the use of the *ccHost* platform[39].

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34 See http://www.creativecommons.org.

35 "[This work led us] to not only build our own agreements to address university-industry transfer but to incorporate two key existing university-university agreements – the Uniform Biological Materials Transfer Agreement (UBMTA) and the Simple Letter Agreement (SLA)" at: http://sciencecommons.org/projects/licensing/.

36 See http://sciencecommons.org/projects/licensing/empirical-data-about-materials-transfer/.

37 See Walsh et al. 2007; Lei et al. 2009; Perry and Krishna 2006; Perryand Krishna 2007.

38 Id.

39 See http://wiki.creativecommons.org/CcHost.

Another major feature of the Science Commons approach, is still connected to the web-based approach that strongly characterizes such initiative, but affects more directly the "generative" moment. As we have pointed out above, one of the limitations of the UBMTA is that it is "monolithic", meaning that a one-fits-all contractual agreement should be used for a variety of situations, and we have already seen how far form the reality this may be. SC offers such *modularity* through a web-based answer-driven form, whereby it is possible to frame the MTA following the needs of the provider. Of course, we are not in presence of an unlimited set of possibilities, as this would not be feasible and would invalidate the effort of reducing the transaction costs connected with endless negotiations and incompatibility of contractual agreements. By trying to create a balanced trade-off between standardization and modularity SC offers to the providers of material a series of options.

By using the relevant web-form[40], the interested provider is asked to insert information that identifies herself and the material, both by content description and by providing an URL. After the identification of the offering party and the object of transaction, the type of offer can be chosen. It is possible to chose between the UBMTA, the Simple Letter, the SC MTA, and finally a Custom Agreement. The latter requires the insertion of an URL that points to an on-line resource containing the relevant agreement. In such case SC offers the support of the meta-data and the web-based advantages set out above. In the former two cases – UBMTA and Simple Letter – the provider will be asked to insert the "Termination date" and the "Transmittal fee", the only two options that those MTAs allow.

The depicted scheme expresses all its potentialities when the provider chooses the Science Commons Material Transfer Agreement (SC MTA). In this eventuality the provider can chose:

- The recipient class (all types, only non-profit, only for-profit);
- Restrictions connected with the use of the material that may relate to:
    - Field of use (all research, restricted to disease, all uses except disease, or restrict to "protocol" where it is possible to enter the protocol description);

40 See http://mta.sciencecommons.org/chooser.

- Whether scaling up is allowed;
- Whether retention of material is allowed;

- Additional informations regarding the offer:
  - Termination date;
  - Transmittal fee.

Upon insertion of such information, the form will automatically generate the contractual agreement implementing all the informations provided, in 3 different formats:
The Science Commons Material Transfer Agreement (the legal code[41]),
the Meta-data (the machine-readable code[42]),
the Commons deed (the human readable code[43]).

Further, an implementing letter is also provided[44]. Finally, the web-based enhanced scheme for wider circulation of material, takes – currently – advantage of the iBridge Network[45], in an effort of creating an on-line portal for the providing and obtaining of the biological materials, on the base of the three different languages of expression we have seen above. Basically, a provider of material can "upload" his material on the iBridge website, and by doing that he will be offered with the chance to choose between the MTAs implemented by the Science Commons project, and will receive an MTA (either the UBMTA or the SCMTA) under the form of a legal code (the MTA), a human readable code (the Commons deed) and a machine readable code (the metadata). Further, such information will be indexed on the iBridge site. In this way, a scientist looking for a material will use the iBridge website as a kind of specialized search engine, where to look for a specific material, with the option to refine the query on the base of the legal terms

41 See http://mta.sciencecommons.org/agreements/sc-ou/2.0/legalcode.

42 See http://mta.sciencecommons.org/chooser.

43 See http://mta.sciencecommons.org/agreements/sc-ou/2.0/.

44 See http://mta.sciencecommons.org/agreements/sc-ns-rd/1.0/letter?source=mta&providerOrg=a&providerAddress1 =a&materialDesc =b&legalURL=agreements/sc-ns-rd/1.0/legalcode

45 http://www.ibridgenetwork.org/

contained on the MTA. In the intentions of the drafters, such scheme, when fully implemented, should prove as efficient as other web-based tools are for books or other physical goods: "We have taken full advantage of Web technology to build a technology infrastructure that can support powerful searching and tracking of available materials. By putting all of these pieces together, we envision our materials transfer system to be one day as efficient as eBay for auctions, or Amazon.com for ordering products, or Google for searching for content"[46].

8 Conclusion

We have observed how in a field where technological innovation develops at an extremely rapid pace, and where advancements in technology allow new discoveries in the biological and genomic sector, science finds itself between openness and closeness. On the one side, there is a basic set of knowledge, especially in the area related to genetics and DNA sequencing, that needs to be free and freely available. On the other side, capitals need to be attracted in order to fund the more expansive projects, that might have only a long-term, eventual success. Intellectual Property, especially in this field, is a contentious issue, meaning that depending on the jurisdiction[47], and in the same jurisdiction, on the courts and on the time[48], a given set of genetics instructions might be deemed patentable or not. However, we observed how, besides and regardless of IP-based concerns, in the specific field of bio-banks and bio-materials transfers, another "enemy" needs to be fought: transaction costs. We reported various sets of data, which confirm the situation: endless negotiations, informational deficits, time and human capitals, incompatibility between different contractual models, lack of standardization, excessive

46 See http://sciencecommons.org/projects/licensing/.

47 See The Trilateral Search Guidebook in Biotechnology 2007.

48 See Sidney A. Diamond, Commissioner of Patents and Trademarks, v. Ananda M. Chakrabarty, et al. 447 U.S. 303; Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911); Commissioner of Patents v. President and Fellows of Harvard College 2002 SCC 76, 219 D.L.R. (4th) 577, 21 C.P.R. (4th) 417, [2004] 235 F.T.R. 214; Association for molecular pathology v. United State Patent and Trademark, 09 Civ. 4515, 2010 (S.D.N.Y.).

rigidity: All these aspects represent another big barrier to scientific collaboration and technological evolution. Efforts to fix the problem are not new, the UBMTA represents a good attempt, and building on it, plus adding digital and web-based advances, currently the Science Commons project seems a very promising model.

However, once again, we cannot confuse the finger with the moon. Contracts are not the goal. Contracts are the tool to achieve a goal that in this case is that of favouring scientific collaboration and technological evolution, by lowering the costs represented by legal barriers (IP) and transaction costs. However, contracts are not the perfect tool, and they suffer from many flaws. We have briefly identified those connected with standard form contracts. More generally, however, we have to recall that access to knowledge and participation to scientific and technological growth are a public policy goal. Hardly they can be achieved through – *only* – a private ordering tool.

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