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Intellectual Property, Open Science and Research Biobanks

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ABSTRACT

In biomedical research and translational medicine, the ancient war between exclusivity (private control over information) and access to information is proposing again on a new battlefield: research biobanks. The latter are becoming increasingly important (one of the ten ideas changing the world, according to Time magazine) since they allow to collect, store and distribute in a secure and professional way a critical mass of human biological samples for research purposes. Tissues and related data are fundamental for the development of the biomedical research and the emerging field of translational medicine: they represent the “raw material” for every kind of biomedical study. For this reason, it is crucial to understand the boundaries of Intellectual Property (IP) in this prickly context. In fact, both data sharing and collaborative research have become an imperative in contemporary open science, whose development depends inextricably on: the opportunities to access and use data, the possibility of sharing practices between communities, the cross-checking of information and results and, chiefly, interactions with experts in different fields of knowledge. Data sharing allows both to spread the costs of analytical results that researchers cannot achieve working individually and, if properly managed, to avoid the duplication of research. These advantages are crucial: access to a common pool of pre-competitive data and the possibility to endorse follow-on research projects are fundamental for the progress of biomedicine. This is why the "open movement" is also spreading in the biobank's field.

After an overview of the complex interactions among the different stakeholders involved in the process of information and data production, as well as of the main obstacles to the promotion of data sharing (i.e., the appropriability of biological samples and information, the privacy of participants, the lack of interoperability), we will firstly clarify some blurring in language, in particular concerning concepts often mixed up, such as “open source” and “open access”. The aim is to understand whether and to what extent we can apply these concepts to the biomedical field. Afterwards, adopting a comparative perspective, we will analyze the main features of the open models – in particular, the Open Research Data model – which have been proposed in literature for the promotion of data sharing in the field of research biobanks.

After such an analysis, we will suggest some recommendations in order to rebalance the clash between exclusivity - the paradigm characterizing the evolution of intellectual property over the last three centuries - and the actual needs for access to knowledge. We argue that the key factor in this balance may come from the right interaction between IP, social norms and contracts. In particular, we need to combine the incentives and the reward mechanisms characterizing scientific communities with data sharing imperative.

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KEYWORDS

Research Biobanks - Comparative Law - Open Science - Open Source - Open Access - Open Research Data - Patent Law - Database Protection - Governance - Social Norms - Privacy - Policy

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Intellectual Property, Open Science and Research Biobanks

*Roberto Caso and Rossana Ducato*¹

1. Introduction

In the last thirty years we have witnessed an overgrowth of Intellectual Property Rights (IPRs) almost in every field of our daily life². According to the traditional view, the protection of IP and the control of information are key to the strategy of many companies and both have been justified with well-known economic and utilitarian arguments³: patent, copyright, trademark and other forms of exclusive rights offer incentives to undertake risky projects,

¹ Roberto Caso is author of paragraphs 1, 2, and 4; Rossana Ducato is author of paragraphs 3, 4.1, 5, 6, and 7; while the concluding remarks are the fruit of a joint reflection of the two authors.

²According to Robert Merges, IP law is like Shanghai or other megacities of the developing world, where new constructions and buildings proliferate everywhere without taking into account the urban planning of the old city. The author concludes his metaphor asserting that: “It’s an exciting time, to be sure; but a confusing time too”. Merges, 2011.

³ See also Ladas, 1929; Plant, 1934; Nordhaus, 1969; Mazzoleni and Nelson, 1998; Menell, 1999; Landes and Posner, 2003.

represent the main source of appropriating returns, can lead to a “more equitable distribution of profits across all stages of R&D”⁴ and are the better antidote for corporate secrecy.

At the same time, the public domain has suffered a slow but constant erosion. Legislators have supported this trend towards privatization, progressively attributing to multiple owners a set of rights to exclude others⁵. Governments have been creating this dangerous dominance through some interventions in patent law and copyright law, such as the Bayh-Dole Act⁶, the Digital Millennium Copyright Act⁷, the Sonny Bono Copyright Extension Act⁸ in the U.S. or Directives 91/250/EEC (replaced by Directive 2009/24/EC)⁹, 96/9/EC¹⁰, 98/44/EC¹¹, 2001/29/EC¹² or

⁴ Heller and Eisenberg, 1998, p. 698.

⁵ See Heller and Eisenberg, 1998; Lessig, 2004; Boyle, 2008.

⁶ Bayh-Dole Act is a watershed from the past patent regimes. First of all, it introduces the possibility of patenting results of publicly funded research. Secondly, it allows university and public laboratories to sell exclusive licenses to private companies or to create partnership with them in order to economically exploit the research results and to translate their basic research into marketable products. See Rai and Eisenberg, 2003; Coriat and Weinstein, 2011.

⁷ Digital Millennium Copyright Act, 17 U.S. Code. This statute has qualified as a criminally relevant behavior the circumvention of technological protection measures and the distribution of tools to encompass DRM.

⁸ Copyright Term Extension Act, 17 U.S. Code, also known as Mickey Mouse Protection Act, extended copyright terms in the U.S.A. as following: duration of copyright protection is raised from 50 to 70 years after the death of the author and it lasts 120 years after creation or 95 years after publication if it is a work of corporate authorship.

⁹ Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs, in Official Journal L 122 of 17 May 1991, replaced by Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs, in Official Journal L 111, 05/05/2009, p. 16–22.

2004/48/EC¹³ in the European Union. Such national or regional legislation is reflected in a number of international provisions like the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (1994) or the World Intellectual Property Organization "Internet" Treaties (WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty), and it has also been confirmed by relevant judicial decisions¹⁴. This progressive

¹⁰ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, in Official Journal L 077 of 27 March 1996.

¹¹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, in Official Journal L 213 of 30 July 1998.

¹² Directive 2001/29/EC of the European Parliament and of the Council on the harmonization of certain aspects of copyright and related rights in the information society, in Official Journal L 167 of 22 June 2001. The importance of IP protection is stressed in whereas 4 and 9.

¹³ Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights, in Official Journal L 157 of 30 April 2004. See whereas 10: "The objective of this Directive is to approximate legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market".

¹⁴ Taking as an example the case law of the United States, because its parabola serves to illustrate the evolution of the trend towards enclosure, regarding patents we can mention *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), affirming that "anything under the sun made by man is patentable", and introducing the patent protection for micro-organism; *State Street Bank and Trust Company v. Signature Financial Group Inc.*, 149 F. 3d 1368 (1998), establishing the patentability of business methods in the United States; Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515 (*Association for Molecular Pathology v. UPO*) overruling the revolutionary judgment of the NY District court which had invalidated the Myriad patents on BRCA gene in virtue of the "product of nature" doctrine. The Court of Appeal overruled the decision of the inferior court and confirmed the principle that isolated DNA is a distinct chemical entity with different physical characteristics from natural DNA, so eligible for patent protection under 35 USC §101. Last

transformation has been creating the conditions for new institutional complementarities between IPR and finance, opening *de facto* to capital the door of the “workshop” of knowledge¹⁵.

A set of interventions in the public and private sector has significantly contributed to this “second enclosure movement”, shifting the balance of power towards private control and increasing the risk of non-use or under-utilization of information¹⁶. In other words, we have such a wide range of Intellectual Property tools that we can no longer manage it.

In this perspective, many authors talk about the tragedy of anticommons. The tragedy of anticommons is a mirror-image of Hardin’s tragedy of the commons¹⁷. According to the American ecologist Hardin, when multiple individuals can use a shared limited resource (in the original example it was an open-access pasture) without the right to exclude others, they tend to act independently and according to their self-interest, exploiting the resource as much

year, the Supreme Court finally ended such dispute with a "salomonic" and controversial decision, stating that the DNA as such cannot be patented, while the so called cDNA (complementary DNA) is a patent-eligible subject matter. *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 12-398 (2013). See, Kesselheim, Cook-Deegan, Winickoff, and Mello, 2013. With regard to copyright *Eldred v. Ashcroft*, 123 S.Ct 769 (2003) is significant, a decision that seems to attribute to Congress the possibility of extending the validity of copyright without apparently any limit (see Samuelson, 2003; Lessig, 2004; Kranich, 2006); more specifically on file sharing, see the famous ruling of *A&M Records v. Napster*, 239 F.3rd 1004 (9th Cir. 2001); *MGM Studios Inc. v. Grokster Ltd*, 545 U.S. 913 (2005).

¹⁵ Coriat and Weinstein, 2011.

¹⁶ Boyle, 2003.

¹⁷ Parisi et al., 2005.

as possible. In this way, the common good is prone to be overgrazed¹⁸; meanwhile, in the tragedy of anticommons the social dilemma is the opposite: the common resource risks being underused because individuals have a right to exclude others and no owner has effectively a privilege of use¹⁹.

The danger of the anticommons tragedy is particularly sharpened in the current biomedical research, the development of which depends inextricably on the opportunity to access and use data, materials, know-how and, consequently, on the possibility of cross-checking pre-competitive information and results.

The scenario described so far gives rise to the risk that rigid and centralized control of information based on many and strong IPRs, shaped on market considerations, invades the proper domain of the scientific community (which is, on the contrary, motivated by the logic of flexible and decentralized control, based on customs and informal norms), decreasing the possibility of access to scientific knowledge.

To counteract this risk, part of the scientific community is promoting the logic of “open intellectual property” to scientific knowledge²⁰. In fact, the emersion of initiatives based on contracts (licenses) such as the Open Source movement or Creative Commons reveals different perspectives with regard to the statutory

¹⁸ Hardin, 1968.

¹⁹ Michelman, 1967; Heller, 1998; Heller, 1999.

²⁰ The "Open approach" to genomic data has been explored by Van Overwalle, 2014.

regime of intellectual property. In the last years the movement of “open intellectual property” is more and more active in the biomedical field.

In biomedical research and translational medicine, the ancient war between the exclusive right (private control over information) and public access to information is struggling on a new battlefield: research biobanks. The latter are becoming increasingly important (one of the ten ideas changing the world, according to *Time* magazine²¹) because they collect, store and distribute in a secure and professional way a critical mass of human biological samples for research purposes. Tissues and related data are fundamental for the development of biomedical research and the emerging field of translational medicine, because they represent the “raw material” for every kind of biomedical study. For this reason it is crucial to understand the boundaries of IP in this prickly context.

After an overview of the complex interactions among the different stakeholders involved in the process of the production of knowledge, in this paper we will thin out some blurring of language concerning concepts often mixed up, such as “open source”, “open access”, and their precipitates. Then, the aim is to understand if we can use the concepts in the biomedical context, and which are the open models proposed in literature specifically for research biobanks in order to avoid the tragedy of anticommons.

²¹

<http://www.time.com/time/specials/packages/completelist/0,29569,1884779,00.html>.

2. The rise of the IP war

The dominions of IP had been constantly expanding insomuch as undermining the flexibility of the scientific social norms. This is evident if we consider, for example, the patent race by academic institutions: there is a tension between the patent requirement of novelty and the need for the scientist to publish as soon as possible. Since the publication of the results frustrates the requirement of novelty, the scientists are prohibited from publishing until the patent is granted²². In the biomedical field, the formalism of law is looked on because it tends to encompass areas that were previously managed in a free and independent way by the whole scientific community, thus changing informal rules and attitudes.

This passage is evident if we compare the famous cases of Henrietta Lacks and John Moore²³. In the first case, scientists who discovered the ‘HeLa’ cells - an immortal cell line derived from the biological samples of the woman – distributed them to all laboratories around the world. In the 50’s those scientists had understood the value of that discovery for the progress of science and they decided to share their results with other peers and potential competitors²⁴. It was a

²² Streitz and Bennet, 2003; Kinney et al, 2004; Murray and Stern, 2007.

²³ Moore v. Regents of University of California, 51 Cal.3d 120, Supreme Court of California, July 9, 1990.

²⁴ Landecker, 1999; O’Brien, 2001; Lucey et al. 2009; Javitt, 2010; Skloot, 2010.

farsighted choice, if we consider that HeLa cells were used in a huge amount of research fields: from polio vaccine to gene mapping; from the development of the first anti-cancer drugs (such as tamoxifen) to space experiments for testing the reactions of the human body to the absence of gravity²⁵.

In the second case, two physicians at UCLA isolated a cell line from the spleen of John Moore and they did not have any hesitation: they rushed to file a patent application on that invention and the Regents of UCLA were designed as assignees of the patent. They immediately started to negotiate agreements with two big pharmaceutical companies for the commercial exploitation of the 'Mo cell'²⁶.

Is it just a coincidence that within three decades researchers have acted so differently? We can try to answer looking at the different role that science has taken over the years. Since the beginning of the 20th Century, science has turned to market, replacing its old form

²⁵ With this statement we do not want to endorse the unethical attitude of researchers towards the patient Henrietta Lacks, but only emphasize the easiness with which they tended to share certain resources.

²⁶ Also in this case everything happened behind the patient's back. The Moore affair gave rise to a long and famous lawsuit: John Moore, after discovering the business built from his cell by Dr. Golde and Dr. Quan, his two physicians at UCLA, tried to sue them for breach of fiduciary duty in the doctor-patient relationship (both had acted without his informed consent), but above all for the recognition of property rights on the patented cell line (he claimed for conversion). About this case, see Annas, 1988; Paganelli, 1989; Hipkens, 1992; Burrow, 1997; Campbell, 2006.

based on the principles of universality and author's prestige with a new form of managerial science characterized by teamwork²⁷.

This change has been speeded up more recently by legislation which has strongly encouraged university and public research centres to patent and to transfer their invention to the industry, also through the use of exclusive licenses (it is the case of the already mentioned Bayh-Dole Act)²⁸. The legislative initiative was welcomed, and has yielded significant benefits in the short term. Before 1980, fewer than 250 patents per year were issued to US universities. After the Bayh-Dole Act, the number of patents increased greatly and university's licensing revenues had grown from \$221 million in 1991, to \$698 million in 1997²⁹. Patents became a source of additional funding and income for universities; at the same time, the network between university and private sector also allowed companies to cut down the costs for research. Just to remain in the area of drug discovery, thanks to the basic research done by universities and the R&D realized by start-ups in order to bring to market academic results, pharmaceutical companies discovered and validated new drug targets in a faster and cheaper way.

This trend toward enclosure, consisting of an elephantiasis in patenting, arises parallel to another front: the access to knowledge

²⁷ Johns, 2009.

²⁸ Heller and Eisenberg, 1998; Mowery, 1998; Caso, 2005; Granieri, 2010; Perkmann and West, 2014

²⁹ Nelson, 2001. Some authors downsized the importance of Bayh-Dole Act in the university patent process. See, for example, Mowery et al., 2004; Mowery and Sampat, 2005.

commons. The prime example is represented by what happened in the United States after the Second World War. At the beginning, public funds were assigned for the creation of the first databases indexing military information, and then also medical and educational data³⁰. Through these funds it was possible to create new research centres and federal libraries. The wind changed when the Reagan administration decided to outsource governmental publications, and some federal programs related to libraries, to the private sector. Even academic institutions followed this path, outsourcing the publication of their journals to private companies. Moreover, the mergers in the 70s between publishers created a situation of oligopoly, so almost all of the scientific production was in the hands of a few big international groups; and consequently the price of scientific journals soared. The conditions for triggering a vicious cycle had been created: at the end universities invested twice for the same thing. In the first instance, they had been investing to fund research that would subsequently be given away for free to publishers; and they invested a second time to regain that same publication, buying for their libraries the subscription to the journal at a higher price³¹.

This evolution in the '80s is crucial because universities and big biotech/pharmaceutical companies started to colonize the area of pre-competitive research and to make access to knowledge more

³⁰ Such as for example, Dialog System. See Summit, 2002.

³¹ Guedon, 2004; Suber, 2004b; Kranich, 2006; Caso, 2009, Reichman, Okediji, 2012.

difficult. Such proliferation of IPRs upstream, while it had a positive effect in the short period, has hindered biomedical research in the long run³². Covering basic research discoveries, materials and reagents with proprietary claims means to inhibit the use of those tools that are fundamental not only for downstream research but also for basic research itself³³. This dangerous stalemate is confirmed by the decrease in the number of new patented drugs notwithstanding the growing public and private investments in drug discovery³⁴. This trend can result from a number of causal factors, but as has been pointed out in the literature, the main contributing causes are the lack of data sharing and the difficulties in governing IPRs³⁵.

3. The role of biobanks in life sciences research

Data sharing and collaborative research have become an imperative in contemporary science, whose development depends inextricably on: the opportunities to access and use data, the possibility of sharing practices between communities, the cross-checking of information and results and, chiefly, interactions with experts in

³² Rai and Eisenberg, 2003.

³³ This recent trend towards the appropriation of data is posing serious obstacles to full and open access to data for scientific purposes. ICSU, 2004.

³⁴ Booth and Zimmel, 2004; Cuatrecasas, 2006; Weigelt, 2009.

³⁵ Weigelt, 2009.

different fields of knowledge. Data sharing allows both to spread the costs of analytical results that researchers cannot achieve working individually and, if properly managed, to avoid the duplication of research. These advantages are crucial: access to a common pool of pre-competitive data and the possibility to endorse follow-on research projects are fundamental for the progress of biomedicine³⁶. This is why new institutions such as research biobanks have gained in importance³⁷.

Biobanks are powerful tools and organizational structures essential for translational medicine and biomedical research, because they are treasures of a pool of pre-competitive information and materials tempting both public research centres and BigPharma³⁸. On the one hand, they are a source of human biological samples stored according to high standards of quality and safety. On the other hand, a biobank is also an informational ‘mine’; in its databases are classified clinical/diagnostic information, sample-derived genetic data, donor's personal data, and the type of consent given for the research. Such data have a surplus value for translational and

³⁶ The point is analyzed by Tomasson, 2009; see also Conley, Doerr, and Vorhaus, 2010 (focusing the data sharing issue in the context of the "Personal Genome Project"); Kaye, 2012 (here the author explores some governance solutions for the privacy protection of the research participants).

³⁷ For a broader overview of the phenomenon of biobanks see Macilotti, 2012.

³⁸ Translational medicine is based on pre-clinical bio-molecular analysis of a critical mass of human biological samples in order to obtain results immediately usable in the clinical context. This allows the identification of biomarkers, i.e. those molecules that can predict the risk of cancer, the presence of a neoplasia and the possibility of identifying the most appropriate and effective drug or treatment for a particular patient. See FitzGerald, 2005.

biomedical research because they are constantly updated with donor's follow-up data: it is possible to follow the clinical history, the disease progression, the response to different therapies, etc. In some cases, research biobanks have also created additional resources such as archives of graphical elaborations of protein structure (in 2-D or 3-D).

Thanks to technological and scientific progress, what until a few decades ago had been considered a worthless hospital waste (a *res derelictae*), nowadays has become an asset in a legal and economic sense. Thereby, the cloud of enclosure is gathering all over these research structures: biological samples are economic assets, subject to the bundle of property rights; genetic sequence derived from the sample could be patented or covered by a trade secret³⁹; biobanks' database can be protected by copyright or EU sui generis right⁴⁰; also some contents of the databases are covered by copyright; the handling of personal data, health records and genetic information must preserve the donor's right to privacy.

Taking into account this panorama, we can distinguish two different levels in the biobank structure, based on the twofold nature of human biological samples. Biobanks, in fact, store a critical mass of tissues (leftover tissues, blood, saliva, urine, etc.) in their bio-

³⁹ The galaxy of intellectual property rights can be configured in a biobank has been described by Dove and Joly, 2012.

⁴⁰ The applicability of the sui generis right to research biobank has been tested in Ducato, 2013. In general, on the EU IPRs regime in the sector of the research data, see Dietr, Guibault, Margoni, Siewicz, Spindler and Wiebe 2013.

repositories; but however numerous they may be, biological samples are still exhaustible resources. They are scarce and rival assets that need to be efficiently allocated among stakeholders. On the contrary, data are “ubiquitous”: they can be replicated ‘n’ times and distributed to ‘n’ researchers at the same time. So, access to biological samples is crucial but access to the information derived from the material support is even more critical to the improvement of collaborative projects. In this paper we will focus only on this second dimension.

Regulatory gaps and the lack of common and shared reference points have been filled by privatization trends, at the expense of the collective good and, in an increasing number of cases, at the expense also of private companies. In particular, traditional models seem to stifle a lot of potential for the biobank activities. For example, the tools ordinarily used for fruition of data and materials, the Material Transfer Agreement (MTA), are cause of unrest among researchers, because of the cumbersome nature of the mechanism, the length of the procedures and the high transaction costs⁴¹. Against this impasse some authors are invoking (and business models are moving towards) the ‘open’ movement⁴².

⁴¹ Streit and Bennett, 2003; Ku, 2007; Rodriguez, 2008; Lei et al., 2009; Noonan, 2009. Specifically on the problems related to MTA and possible solutions offered by Science Commons, see Margoni, 2013.

⁴² Hess and Ostrom, 2007; Hope, 2008; Edwards et al. 2009, Weigelt, 2009, Lei et al., 2009; De Robbio and Corradi, 2010. For a precise description of the "open business models" see Chesbrough, 2006.

4. "Open Science": framing a slippery concept

The vision that closed model systems, and patents in particular, encourage an efficient management of research, balancing the return on investments and the benefits for the whole community, has been strongly challenged in recent years⁴³. This change is evidenced not only by the signal given by some 'rebel' researchers (e.g. Ilaria Capua)⁴⁴, but even by big pharmaceutical companies (e.g. Novartis and Glaxo-SmithKline)⁴⁵. BigScience becomes 'open' certainly not because of altruism: simply, they realized that cooperation is more convenient than competition based on IPRs. Despite the "openness" is a trend that is spreading in several areas, the core of the concept is vague and it is currently used for describing a varied landscape. As Maurer affirmed: "Open science is variously defined, but tends to connote (a) full, frank, and timely publication of results, (b) absence of intellectual property restrictions, and (c) radically increased pre- and post-publication

⁴³ Kitch, 1977. With regard to the meaning of "openness" see Fecher and Friesike, 2013; Destro Bisol et al., 2014.

⁴⁴ The Italian virologist identified the genetic sequence of the avian flu virus and decided to make it available to the worldwide scientific community by uploading it to GenBank, disregarding the invitation of the WHO to file it in a limited-access database. See Enserink, 2006.

⁴⁵ Strauss, 2010.

transparency of data, activities, and deliberations within research groups"⁴⁶.

What is certain is that the concept did not originate in the legal field, but it has been internalized in the legal thought as a result of a movement coming from two different technologies.

Then, to understand what it means "open science" and how is spreading to the realm of biotechnology⁴⁷, we have to contextualize the original concept of 'open source' in the world of software and the notion of "open access" in the context of scientific publications. Afterwards, we will discuss whether such concepts work if applied to scientific research in the 'bio-' fields⁴⁸.

4.1. Open Source and Open Access

Open Source is a revolutionary and provocative concept, developed since the early '70s as part of computer science, and it represents a new way of thinking about computer programming and software in its entirety: from conception to final release and distribution. This movement is composed of two different souls: Free Software and Open Source Software. The first is linked to the name of Richard

⁴⁶ Maurer, 2003.

⁴⁷ Delfanti, 2013.

⁴⁸ The following classifications were presented by Prof. Richard Gold during the seminar "Models for Sharing Data" within the Biobank Lab, held at the University of Trento in May 2010.

Stallman⁴⁹ and has an ethical aim. According to free software philosophy, proprietary software is a social problem that shakes the values of communality and sharing to its foundations. Software must be freely available and accessible without restraints as a desirable social outcome. On the contrary, Open Source Software is a definition created in 1998 on the occasion of the release of the source code of Netscape's browser by Eric Raymond. According to these alternative currents, open source is a more efficient choice if compared to the traditional closed model⁵⁰. The collaboration of different programmers, who at the same time are users, and the decentralized production monitored by strong expectations and sanctions are a synonym of quality, and they also reduce the costs and the time for the product development.

Unless the starting point is different (the former school has a more philosophical and political approach, whereas the latter has a more utilitarian vision), the pragmatic result is the same. In fact, according to both Free Software and Open Source Software, in addition to the object-code (the machine-readable format) the source code is also distributed (the 'human language') to the public of user-

⁴⁹ In 1983 he announced the GNU project, an operative system compatible with Unix, the proprietary software more widespread in research laboratories in American universities. Stallman's novel idea consisted in the creation of a license (copyleft, "all rights reversed") giving much more power to the user than to the owner. About the origins of free software, see Stallman, 2002.

programmers⁵¹. In this way they can both use the software, and copy, modify and redistribute it⁵². According to the General Public License manifesto, free software gives users the four "fundamental freedoms": 0) run the program, for any purpose; 1) study how the program works, and change it to make it do what you wish; 2) redistribute copies; 3) distribute copies of your modified versions to others.

Both 'open projects' are distinguished by a special legal regime that allows progressive developments. The GNU GPL, in fact, is a viral license because it "infects" all subsequent products containing the original code: the programmer gives up IP exploitation to follow-on users as the latter are not allowed to distribute the modified software with a proprietary license.

It is hardly necessary to point out that this movement is not the negation of intellectual property, but rather represents a new way of interpreting it. It would be a mistake to think that copyleft means the absence of copyright. Viral licensing is properly designed under copyright law, but it allows users to modularize the availability and distribution of their works, while also posing some limits and obligations.

⁵¹ A way to overcome this problem is a particular technique called reverse engineering, where the reverser analyzes the programs and tries to understand how they work without having the source code. See Lessig, 1999; Nichols and Twidale, 2003.

⁵² Stallman, 2004.

A concept that is often confused with the Open Source movement, but we have to keep conceptually distinct, is that of “Open Access (OA)”. Such an acronym indicates a literature that is “digital, online, free of charge, and free of most copyright and licensing restrictions”⁵³. In the OA context two different routes have been distinguished, regularly labeled as “gold road” and “green road”⁵⁴. The first one refers to OA journals; the second one to self-archiving previous published works.

In a nutshell, the core of OA works as follows: the institution shall pay the cost of the publication of its researcher, who retains some rights (authorship, in particular) and surrenders others - throughout licenses such as Creative Commons⁵⁵ – in order to make the publication freely available⁵⁶. Here, production costs are borne by the authors and institutions, while distribution costs – held down thanks to digitization - are shared with new intermediaries.

At the end, OA reduces costs, circumvents the limits imposed by increasingly stringent regulations on copyright, licensing agreements and Digital Rights Management (DRM). OA offers also reputational incentives, because it represents a means to disseminate authors’

⁵³ Suber, 2012; see also Willinsky, 2006; for an update literature review on the Open Access see Frosio, 2014.

⁵⁴ Harnad, Brody, Vallieres, Carr, Hitchcock, Gingras, Oppenheim, Stamerjoans and Hilf, 2004; Guédon, 2004.

⁵⁵ Creative Commons (CC) is a charitable corporation that promotes the sharing and circulation of knowledge in compliance with copyright law. Although it offers standardized models, its modular licenses (attribution, noncommercial, no derivative works, share alike) and their combinations can provide flexibility in setting the interests of parties. Source: <http://creativecommons.org/>.

⁵⁶ Caso, 2009.

ideas, to spread their intellectual production, to promote themselves before other peers; but it is also a tool to get free and quick access to the literature necessary for implementing and deepening their own scientific production. OA is also an opportunity for libraries to mitigate the costs of journals and subscriptions⁵⁷. Also, society and the progress of knowledge, in general, can benefit from such a system because the openness is the primary method for correcting errors and mistakes through the sociological mechanisms of peer review and citation⁵⁸.

However, authors play the key role in building a system based on open access, as the fate (open or closed) of their works is in their hands. It is a cultural problem (in the sense that part of scientific community still ignores what OA is) but is also a challenge to remove the existing disincentives (such as the Ingelfinger rule) and to find those incentives that could propitiate this mentality⁵⁹.

5. "Biotechnology Unchained": the tool of the "open patent"

In the field of biomedical research and drug discovery, the open source philosophy has been transposed into "open source biotechnology"⁶⁰. Of course such a transplant is not a trivial

⁵⁷ De Robbio, 2010.

⁵⁸ Boyle, 1997.

⁵⁹ Suber, 2004a.

⁶⁰ Feldman and Nelson, 2008; Gitter, 2013.

question because the Open Source model and Open Source licensing have been developed around the idea and the structure of copyright. Instead, in what have been called open biotechnology, we have to deal with patents.

At first sight, *open source patent* may seem a tautological expression, because the information related to the invention is already publicly accessible and available through the mechanisms of disclosure or deposit⁶¹. It implies that, even though the invention is disclosed, the information and data embodied are excludable. Patent itself may inhibit the public use of that invention through exclusive licenses. In this context, ‘open source’ refers to an issue of accessibility rather than disclosure⁶².

Taking ideals behind the Free Software movement, the Open Source patenting develops “the aspirational goal of biological scientists [to] closely track those of the open source community in desiring to keep information and discoveries communal and accessible”⁶³. Here, the ‘viral’ license works in the following terms: the licensees cannot appropriate the fundamental ‘kernel’ of the technology and any development must be shared at the same terms of the original technology⁶⁴; data and results of research should fall into the public domain, but under certain requirements, for

⁶¹ Dasgupta and David, 1987.

⁶² Boettinger and Burk, 2004.

⁶³ Ibid., p. 225.

⁶⁴ See BIOS concordance. Also Feldman, 2004; Feldman and Nelson, 2008; Torrance, 2009.

example, by waiving an "unfair" use of IPRs. The participants in the Open Source project, therefore, would agree to grant licenses or to exercise their rights in order to make inventions and improvements available to the whole community⁶⁵. In this scenario, the patent holder should license the invention with a license that protects those technical solutions and improvements from possible attempts of appropriation, for example by commercial competitors.

The main example of this philosophy is BIOS's CAMBIA, an Australian nonprofit research institute that has extended this model to the transfer of biological samples⁶⁶. Users of the BIOS 'concordance' do not assert IP rights against each other's use of the technology, materials and methods to do research, or to develop products either for profit or for the public good. Consequently, the improvements must be shared according to a BIOS license, while the products and inventions developed from the same technology can be patented. In the latter case, however, the improvements that have been patented must return (grant back clause) to the BIOS and to other licensees on the same terms of the original license or must be freely cross-licensed.

Some scholars have emphasized the advantages of this approach⁶⁷. In fact, the absence of IP incomes is counterbalanced by a social

⁶⁵ About the adoption of the open source model in the biotech field, Hope, 2008.

⁶⁶ BIOS stands for "Biological Innovation for Open Society) <http://www.bios.net/daisy/bios/home.html>

⁶⁷ In particular, it is possible to see the echo of the open source approach in the theorization of Parchomovsky and Mattioli, 2011. The authors propose two new types of patents - the "quasi patent" and the "semi-patent" - specifically thought

recognition for the participants⁶⁸. This can also mean economic rewards in terms of future job offers, proposals for collaboration in commercial open source companies and access to venture capital market⁶⁹.

However, the adoption of this system does not dissolve some key issues and the translation of the open source model outside the field of information technology raises a series of challenges⁷⁰. First of all, there is a huge difference in the investments for R&D between the informatics and the biotech context⁷¹. Biotechnological research implies exorbitant costs for drug discovery processes, clinical trials, intellectual property management⁷². This factor can influence the social norms and the scientific behaviors toward the discovery process: the programmer could be more proactive in sharing his information while the researcher could adopt a more defensive approach towards his precious set of data⁷³.

The economic cost is not the only factor able to differentiate the two fields: the time is another key issue. Unlike what happens in programming, in biomedical research the process from discovery to marketing can take years or may not ever arrive at a marketable result.

for the biobanks sector. According to them, both patents would be compatible with the USPTO system and would mitigate the problem of patents related costs.

⁶⁸ von Hippel and von Krogh, 2003.

⁶⁹ Chakravarty, Haruvy and Wu, 2007; Hope, 2008.

⁷⁰ As pointed out by Boettinger and Burke, 2004.

⁷¹ Lerner and Tirole, 2005; Torrance, 2009.

⁷² de Beer, 2005.

⁷³ Gitter, 2013; Nicol, Caruso, and Archambault, 2013.

Therefore, the transplant of the Open Source philosophy in biotechnology would run a high risk of rejection. Open Source is a culture of sharing developed in the hacker community with different needs from the biotech world. Open Source, therefore, may not provide the right incentives for effective collaborative research⁷⁴.

6. Legal tools for opening the doors of biobanks

Research biobanks have been metaphorically described as a library. This comparison is not so abstract since biobanks have both physical databases and digital archives.

Digital databases of the biobanks may contain a variety of information. First of all, information related to the 'owner' of the sample like personal and clinical data, and additional information such as eating, life or relationship habits. Biobanks' databases can also index information derived from the material support, i.e. genetic data or sensitive information that can reveal the health conditions of the patient. In particular, genetic data are a very peculiar category because they concern not only the person they belong to but also his entire biological family. Quite often biobanks proceed to aggregate the data and to make the first analysis. Therefore the results of these analyses and the generated cohorts

⁷⁴ As affirmed by Gold, 2013.

are included in digital files and stored in the archive for following research. We have also to consider that many biobanks are now linking their databases to the electronic health records of patients, thus creating a resource that contains a huge amount of data, constantly updated, reliable, and collected from healthcare professionals⁷⁵.

Moreover, since the main purpose of a biobank is to provide samples and data to researchers, while one of the main bonds of the latter is the reporting of his activities and the grant back of analysis' results, biobanks also collect the research reports and, if available, the publication derived from the study of the biological and informational resources provided.

Within the digital archives of the biobank can therefore be stored copyrighted materials, and simple data. Regarding researchers' reports and publication, the new methods offered by the Open Access in the field of scientific and academic commons (OpenWetWare⁷⁶, PLoS⁷⁷, Open Archive Initiative⁷⁸, etc.) represent a great chance to transform research biobanks into an invaluable resource and a reference point.

Concerning the diffusion of raw data, things may be a little bit different⁷⁹. Since 2012, the Open Knowledge Foundation is carrying

⁷⁵ Guarda, 2013.

⁷⁶ <http://www.openwetware.org/>.

⁷⁷ <http://www.plos.org/>.

⁷⁸ <http://www.openarchives.org/>.

⁷⁹ See, e.g., Reichman, Uhler, 2003; Borgman, 2007, p. 115; The Royal Society Science Policy Centre, 2012.

out a project on "Open Data"⁸⁰. The latter is the last application of the logic of "openness" in relation to data and content, and it can be summarized in the following terms: "Open data is data that can be freely used, re-used and redistributed by anyone - subject only, at most, to the requirement to attribute and share-alike"⁸¹. Moving from the awareness of the need of data's interoperability, the project provides a variety of waivers and licenses specifically suited for data⁸². One specific pilot is dedicated to the openness in science and research, where the working group encourages the sharing of publicly-funded research data (such as the results of medical trials, successful or otherwise) placing them in the Public Domain via PDDL or CC0⁸³.

7. Open models and collaborative projects in the field of the life sciences

Unless Open Data initiatives offers a valid legal tool, but they does not offer per se incentives to ensure their using by a single researcher⁸⁴. They are likely to be abandoned if appropriate

⁸⁰ This initiative has thus passed the open access protocols that were previously developed by Science Commons, which has now been re-integrated with Creative Commons <http://sciencecommons.org/projects/publishing/open-access-data-protocol/>.

⁸¹ See <http://opendefinition.org/>.

⁸² For a complete overview: <http://opendefinition.org/licenses/#Data>.

⁸³ See the "Panton Principles" for ensuring open data in science: <http://pantonprinciples.org/>.

⁸⁴ On the incentives moving researchers see Borgman, 2007.

structures of governance are not established in order to allow their sustainability. It is necessary to involve all stakeholders in the design and management of these innovative projects, facilitating dialogue, participation and transparency⁸⁵.

In response to this gap, new paradigms are emerging for access to pre-competitive information, such as collaborative partnerships. Many new cases of private-public collaboration are demonstrating their value and biobanks may claim their IP power on them.

One of the first example in this sense is represented by the ‘HapMap Project’⁸⁶, an international consortium involving ten research centres located in Japan, the UK, Canada, Nigeria, China and the USA. Its scope was to create a map of genetic variations in human beings - in order to offer a valid instrument in support of biomedical and clinical research - and make this information freely available. According to the Data Release Policies, in fact, all data generated must be released “quickly”⁸⁷ in the public domain. The user accepts the terms of this agreement through a “click-wrap” license. In this way, the database is freely accessible to all bona fide researchers and users cannot tie down data and information by

⁸⁵ Kranich, 2006.

⁸⁶ International HapMap Project, <http://hapmap.ncbi.nlm.nih.gov/>. See also Aa.Vv., 2003.

⁸⁷ See <http://hapmap.ncbi.nlm.nih.gov/datareleasepolicy.html>. It is not well specified how quick the release into the public domain has to be.

filing ‘patent parasite’⁸⁸ application over the resulting discoveries. Researchers are forced to share information among the participants in the HapMap project, so bound by the same contractual provisions. In any case, the possibility of patenting is not excluded *a priori*: if it is possible to show a specific utility, researchers can apply for a patent “as long as this action does not prevent others from obtaining access to data from the Project”⁸⁹, licensing the invention so that the information used is still accessible to other participants. More recently, other articulated solutions have emerged, such as the Structural Genomic Consortium (SGC)⁹⁰, Sage Bionetworks⁹¹, the European Bioinformatics Institute (EBI) Industry Programme⁹², the Predictive Safety Testing Consortium (PSTC)⁹³, the International Union of Basic and Clinical Pharmacology (IUPHAR)⁹⁴, Life

⁸⁸ According to Daniel de Beer a ‘patent parasite’ is a patent developed from the original material “to which just a tiny change has been made”. De Beer, 2005, p. 366.

⁸⁹ HapMap Project, Data Release Policies.

⁹⁰ <http://www.thesgc.org/>. SGC is a non-profit organization founded in 2004 with the aim of promoting the development of new drugs, investing in basic research and releasing to the public every type of information (from reagents to know-how) The SGC's primary goal is to determine the three-dimensional structure of proteins, in order to understand the molecular mechanisms of their biological function. Then, the data obtained are deposited in the Protein Data Bank (PDB), a freely accessible archive, which since 1971 collects information about 3D structures of large molecules, including proteins and nucleic acids (<http://www.pdb.org/pdb/home/home.do>).

⁹¹ <http://sagebase.org/>.

⁹² <http://www.ebi.ac.uk/>.

⁹³ <http://c-path.org/pstc.cfm>.

⁹⁴ <http://www.iuphar.org/>.

Science Grid – Eli Lilly, Pistoia⁹⁵ and Innovative Medicines Initiative (IMI)⁹⁶.

These new business models are developing the idea of open innovation in the area of biomedical research⁹⁷. That was expressly declared by Weigelt and Edwards when they launched SGC, an innovative project to foster the free circulation of pre-competitive data, based on the osmosis between private and public sector and the adoption of open access structures⁹⁸. According to SGC Data Policies, all products and results (material and know-how) are released into the public domain, but the enforcement of this system is secured by a participatory and transparent governance structure, a number of clear operational rules and legal instruments, such as the adoption of CC licenses for the exchange of pre-competitive information⁹⁹.

Sage Bionetworks is another example in this sense. It is a not for profit organization founded in Seattle in 2009 with an ambitious goal: to create a "digital Commons" where computational biologists can improve an integrative bionetwork in order to expedite the pathway to knowledge, treatment, and prevention of disease (1st Sage Bionetworks Commons principle). The purpose is to build an innovation space where scientists are not limited to aseptically

⁹⁵ <http://www.pistoiaalliance.org/>.

⁹⁶ <http://www.imi.europa.eu/>.

⁹⁷ Chesbrough, 2003.

⁹⁸ Edwards at al., 2009; Weigelt, 2009.

⁹⁹ Edwards at al., 2009.

exchange data, but, as active participants, they are calling to create new tools (models disease) or improve those developed by other colleagues¹⁰⁰. So through an open IT infrastructure (the Sage Bionetworks Platform), standard tool-sharing mechanisms, secure measures and a cloud computing system, this model aims to become a powerful resource for data sharing and interoperability of different data sets. From the legal point of view, such goal has been pushed through the application of the CC Attribution Unported License for creative works and the CCO for data.

On another side, this context is emblematic because highlights a latent tension: the values of open data are potentially in conflict with those of privacy. Information that is used in this kind of projects can also lie in personal data.

In this sense, Sage Bionetworks has developed, based on the idea of Lunshof et al.¹⁰¹, a model of "Portable Legal Consent" (PLC), that is a "standardized informed consent system for anyone who has obtained data relevant to their health and would like to donate that data for research purposes"¹⁰². Data collected under these terms, if correctly de-identified, can be used and reuse without additional permission by all researchers who agrees both to protect the research participants and permit the public access to their results. The peculiar feature of this experimental bioethics protocol is the

¹⁰⁰ Derry et al., 2012.

¹⁰¹ Lunshof, Chadwick, Vorhaus, Church, 2008.

¹⁰² <http://sagecongress.org/WP/wp-content/uploads/2012/04/PortableLegalConsentOverview.pdf>

conscious involvement of patients: they are fully advised that the de-identification is not a complete and irreversible anonymisation; the development of the technology and the techniques of data aggregation can make intelligible what was not in accordance with the highest standards of protection adopted until some time ago. In this perpetual chase, Sage Bionetworks cannot assured a full protection against the loss of confidentiality. The patient who wants to participate must therefore be aware of the possible risks, predictable and not, that the online sharing of their DNA may result.

Probably Sage Bionetworks is one the model which better interprets the democratization of innovation imagined by von Hippel, although we must admit that some of its solutions could create some frictions if applied in Europe, especially if we consider the implications of PLC for data protection law¹⁰³.

8. Concluding remarks: making the case for biobanks

The English word “biobank” has in itself a theme connected to the world of finance (bank). In Italian we use the term "bioteca" which clearly has a resonance with the word “biblioteca” (library). It is a terminological choice suggesting a paradigm shift. The enclosure movement is dramatically expanding its borders to crucial

¹⁰³ von Hippel, 2005.

sectors of innovation such as the pre-competitive area and is trying to colonize strategic structures like research biobanks. In this sense, the latter, like real banks, risk being transformed into a *caveau*¹⁰⁴. Scholars have warned against this dangerous drift, underling the institutional and public role of biobanks: the latter is the steward of a critical mass of material and information, fundamental for biomedicine and translation medicine, which have to be used in a far-seeing and efficient way¹⁰⁵.

How to build this knowledge commons of the 21st Century?

First of all, lawyers and policy makers should consider how the components of IP, technology, social norm and contracts interact in the specific context of research biobanks. As we have already emphasized, the biobank has a dual nature: a material and informational one. Therefore, the exchange of biological materials will be managed through an MTA, while for the data appropriate access policies must be created¹⁰⁶.

¹⁰⁴ De Robbio, 2010.

¹⁰⁵ According to the idea for the creation of knowledge commons through institutions and collective actions as outlined in Hess, Ostrom, 2007. See also Madison, Frischmann and Strandburg, 2010.

¹⁰⁶ The contractual component is the ideal solution in order to settle the parties' interests, but in the biobank context MTA is more the problem than the cure. Collaborative initiatives such as Science Commons have offered contractual models to make the transfer of research materials easier, thanks to a flexible, modular, web-based and user-friendly tool. However, this MTA has the usual disadvantages of standard agreement and its modularity partially alleviates the problem by providing a limited space for autonomy. On the one hand, standardization helps to reduce transaction costs and to facilitate circulation, but on the other hand, it creates difficulties in the field of open licences. Furthermore, a standard contract is always deficient in participatory aspects, because the

Why should researchers share information with others?¹⁰⁷ Although the benefits of data sharing are universally recognized¹⁰⁸, the development of this process still faces technical and, above all, cultural problems¹⁰⁹. At the same time, the abolition of the system of IPRs could not constitute an efficient response¹¹⁰. In order to elaborate possible solutions, firstly we must play on reputation and authorship, the unmoved mover of the openness of information. Scientific data sharing must be encouraged by creating appropriate reputational incentives, like a sort of h-index. The more you share with biobanks and the scientific community, the more you are cited and the more are the benefits. A researcher with a higher h-index could have priority access to material resources (biological samples) over other colleagues. Of course, access to immaterial resources of the biobanks should be granted for any research purposes, as broadly as possible, to all bona fide scientists, just after an online registration.

The same 'feedback' incentive could be a valid tool also for the biobank itself and can address its funding problems. In the context

contents of the agreement do not result from a negotiation, but it is unilaterally imposed. On the problems related to the standardization of contracts, see Roppo, 1975; Boggiano, 1991; Alpa and Bessone, 1997.

¹⁰⁷ See Borgman, 2007.

¹⁰⁸ Hess and Ostrom, 2003; Collins, 2010; Brooksbank, Todd Bergman, Apweiler, Birney and Thornton, 2014; Choudhury, Fishman, McGowan and Juengst, 2014 (with regard to the importance of the sharing of data collection in neuroscience).

¹⁰⁹ An interesting analysis is presented by Andreoli Versbach and Mueller-Langer, 2013.

¹¹⁰ Merges, 2004.

of EU projects¹¹¹, Anne Cambon-Thomsen has proposed the creation of a BRIF (*Bioresource Research Impact Factor*), a special citation impact factor in the case of biobanks¹¹². Such a metrics should "trace the quantitative use of a bioresource, the kind of research using it and the efforts of the people and institutions that construct it and make it available", giving credit to those who created and maintained a valid resource.

In order to spread data sharing, some authors have also proposed the adoption of a "grant back" clause: the researcher who uses a biobank should submit periodical reports as well as the results obtained¹¹³. However, this solution might turn into a disincentive because ethically controversial (it would force the self-determination of a researcher) and potentially inefficient (if a researcher is forced to share a result he may choose to use another resource that does not impose such a condition). In this sense, the US National Institutes of Health (NIH) have developed a temperament of the grant back clause: the investigator, who is performing genome-wide association studies with NIH fundings, must insert his data set into the NIH database of Genotypes and Phenotypes, but at the same time the NIH guarantee the exclusive right to publish the analysis and the results obtained by the dataset during a period of six

¹¹¹ <http://www.gen2phen.org/groups/brif-bio-resource-impact-factor>.

¹¹² Cambon-Thomsen, Thorisson and Mabile, 2011. Ut represents the evolution of the BIF, Biobank impact factor proposed bu Cambon-Thomsen, 2003. See also, De Castro, Calzolari, Napolitani, Rossi, Mabile, Cambon-Thomsen and Bravo, 2013.

¹¹³ As already mentioned about the "HapMap Project".

months¹¹⁴. This balancing solution is based on the assumption that data derived from GWAS studies are pre-competitive and, therefore, a strong provision favouring its "enclosure" would block patents, downstream discoveries and future research¹¹⁵.

These recent trends towards openness show fascinating perspectives but may paradoxically become a closure unless we learn to handle all these new possibilities. Lawyers must return to being the finest interpreters of contract law, in order to modulate a system of incentives that take into account the following steps: defining the organization (public, private or partnership); establishing the governance structure and transparent data access policies; engaging patients and research participants; elaborating types of contracts and licences, considering the dual nature of the biobank and consequently the different object (digital information or biological material). The complexity lies in the management of the interface between copyright and patent. It represents the main challenge of this contractual drafting where lawyers still have something to say.

¹¹⁴ The NIH Genomic Data Sharing Policy has been recently updated (August 28, 2014). See the new version here: <http://gds.nih.gov/03policy2.html>. Before such a modification, the period of exclusivity was up to twelve months.

¹¹⁵ <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

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