

Chapter 1

Introduction: A Law and Technology Approach to the Law of Biobanking

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This book constitutes the proceedings of the International Conference entitled “Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology”, held in Trento, in May 2010. The Conference saw the participation of eminent scholars from Italy, US, UK, Canada, Germany, and France that gave rise to an engaging debate about the legal issue related to the biobanks.

This event was organised by the *Trento LawTech Research Group*,¹ a research team established at the Department of Legal Science of the University of Trento. In general, the group has a primary aim of exploring the complex interactions between law and technology. In particular, it has a special focus on the peculiar field of the biobanking technology.

The idea of exploring the relationship between law and technologies originates from the belief that for a deeper understanding of a given technological phenomenon, a strictly legal analysis is not sufficient. Instead, it is necessary to embrace an overall approach in order to combine the technical and social analyses of the phenomenon with the legal one.

It is self-evident that in nature, there are only “phenomena” and the distinction between legal, social, and technical aspects is only a *fictio*, which is functional to study these phenomena. The legal analysis represents only one factor for the comprehension of the “technological fact”, and this analysis must be combined with the results of the studies conducted by other disciplines to understand the phenomenon. Therefore, a multidisciplinary approach is an “imperative” and the main issue is to find a method and a language that can be used in communicating with the different sciences involved.

¹ <http://www.lawtech.jus.unitn.it/>.

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Every science has its own technical language and its own point of view, but all sciences share the same “fact”. Therefore, one safe starting point is the analysis of the fact. Nowadays, technology grows fast and the understanding of the “technological fact” becomes increasingly complex and requires the constant support of experts in the specific field involved. On one hand, the necessary recourse to the experts implies the risk of increasing the fragmentation of the knowledge, but from the other hand, it pushes (even) the legal scholars to invest more energy into the debate with the other branches of science. In particular, the complexity of “technological phenomena” highlights the needs for the jurists to acquire the fundamental technical notions of the phenomenon that they intend to study. Examples of this fact are innumerable in the field of human biotechnology. One glaring instance is the famous and controversial judgement of Judge Swift in the case *Association for Molecular Pathology, et al. v. USPTO*, which has been carefully analysed in one of the contributions proposed here. In this case, Swift spent most part of the judgement in the explanation of the biological characteristics of DNA, an essential premise to understand the meaning and the consequences of the patent on DNA.

Against this backdrop, this book bucks for representing an occasion of the debate about law and technology through the analysis of the legal issues related to a peculiar “technological fact”, the “research biobanks”, a phenomenon which has become increasingly relevant in the medical research landscape.

Before exploring the structure of this book, it appears relevant to investigate more deeply into the complex relationship between law and technology, starting from the thesis developed by the Trento LawTech research group.

As a first remark, it is worth noting that if, on one hand, law is used for the regulation of technology; on the other hand, law employs technologies to pursue its own goals, the relationship is bidirectional. We may observe this feature in different contexts.

Firstly, technology may change the contents of protected legal interests. One clear example is the right to privacy, which has been transformed by the rise of IT from the “right to be let alone” to the “right of controlling the information” pertaining to the individual (so-called right of “informational self-determination”). In the biobank context, this aspect assumes a crucial role. As we will appreciate, by virtue of the change of contents of the right to privacy, persons involved in the biobanking are not only entitled to the right to be protected from illegitimate intrusion, they also have the right to control the data stored in the biobank and eventually to withdraw their consent. In biobanking, the right of “informational self-determination” constitutes the rationale that gives rise to the debate between scholars who deem it necessary to obtain a strict consent for every use of tissue and data and scholars who consider a broad consent sufficient. Secondly, the emergence of new technologies can transform well-established scenarios. If, in the past, the research opportunities were limited by the possession of adequate numbers of biological samples, biobanks permit a greater number of researchers to have access to biological resources and facilitate data sharing between researchers. As we can appreciate in the articles concerning open-access in biobanking, the biobanks could unhinge the “market” of medical research, thus, making it more competitive.

Thirdly, the features characterising a given technology shape the rules linked to this technology. It is one thing to have rules concerning a material entity; it is another to have rules concerning the bits. In some cases, this implies the need to re-frame concepts that traditionally refer to material things, such as ownership and possession, and to draw on new concepts shaped on the reality of the immaterial entities. As it can be verified in some contributions of this book, the double dimension of human tissue, both material entity and source of genetic data, represents the main challenge in the definition of the legal status of human tissue. This double dimension stresses the need to create a new legal paradigm to define the relationship between person and human tissue detached from his body. Whilst tissue is commonly referred to property rights, the information obtained from tissues are not considered as property and their protection is based on the protection of personality rights.

Fourthly, technologies create new commodities and the law is continuously faced with the need to regulate these commodities, which were unknown in the past. Biobanks *per se* could be seen as a new “commodity”, even if a particular one. Some contributions of this book clearly portray the new challenges related to the access to this new commodity and the efforts that numerous legislators are spending to regulate it. The difficulty to provide a regulation derives from the crisis of the classical categories of law that seem unable to encompass the new issues raised by this phenomenon. The new interests linked to human tissues and their crucial role in the biomedical research transform the concept of “human body” and create an inedited tension between the interests of the medical research, the interests of the market, and the protection of human dignity.

Fifthly, the development of new technologies also influences the source and the structure of the rules. In the biobanks context, this feature is particularly evident. The reconstruction of the regulatory landscape shows that in this field we assist to a constant overlap of regulations made by international entities and national institutions with guidelines and best practise written by technical committees and other stakeholders. It seems increasingly difficult for the operators who work in the biobanking to “juggle” in this “tangle” of regulatory instruments and technical norms. This aspect is underlined in the major part of the contributions and highlights the need to rationalise the regulatory framework.

Moreover, in the European countries, the lack of harmonised legislation in this matter represents an obstacle in building common scientific infrastructures and suggests the need for an intervention of the European legislator.

Sixthly, technology not only changes the law setting, but also sometimes guarantees the enforcement of the norms. In biobanking, one of the clearer examples of this fact is the encryption and anonymisation systems that are used to ensure that the privacy of the people involved is respected. These technological measures reduce the risks related to the spread of data and enable the building of a safe environment for data sharing.

IT systems increasingly assume a pivotal role in the governance of biobanks. The P3G and EnCoRe projects, for instance, prove the trend of using technology to assure the exercise of patients’ rights (the right to withdraw the consent, the right to

control the data flow, and the right to know in which research project tissue and data are used), embedding the legal norms into the technological infrastructures. Technology achieves levels of protection and interaction that law instruments solely cannot assure. Law and technology become two complementary factors for protection and promotion of the patients' rights in medical research.

As to the analysis of the structure of the book, it seems important to state that every essay presents an autonomous point of view, and, in some case, the views differ, which is normal in debate. The scope of this volume is not to underpin a particular thesis, but to give an account of the debate that has arisen in the biobanking context, and above all, to put on the arena some original ideas and re-interpretations of old questions.

This book is composed of three parts. The first one is devoted to the analysis of the issues related to property and privacy in the biobanking context. These themes are analysed from different perspectives. Below is a brief excursus of the contributions.

The contribution of Stephen Munzer introduces us in the discussion about research biobanks and synthetic-biology repositories with respect to autonomy and ownership, through a detailed examination of a pair of examples, the autonomy-based interests of the Havasupai Indians in their blood samples, and ownership structures for zinc finger proteins.

Starting from another perspective, Roger Brownsword draws a larger regulatory picture of biobanking, with its own triple bottom line (i) that participation and the use of participants' samples and data are based on free and informed consent; (ii) that the privacy, confidentiality, and fair data processing rights of participants are respected; and (iii) that the proprietary rights (if any) of participants are respected.

The article of Eric Feldman and Chelsea Darnell focuses the attention on the US Genetic Information Nondiscrimination Act (GINA) and its consequence on biobanking. In particular, the Authors, moving from the question does genetic information warrant special legal protection, and if so, how should it be protected, analyse how GINA regulates genetic information, and conclude with the provoking assumption that GINA seems to be a "solution in search of a problem", an "unnecessary piece of legislation that creates more problems than it solves".

The contribution proposed by Naomi Hawkins et al., offers an interesting analysis about the ownership of biomedical information in biobanks. Through a careful study of the concept of property applied to the biomedical information, the authors show that, "the notion of ownership of information in the context of translational research in genomics is legally meaningless". In particular, they conclude by establishing that, "[T]here is no such thing as ownership of information as a matter of law, and to discuss such matters using the language of property does not benefit any of the parties involved in research, whether they are participants, researchers, research institutions or research funders".

In her essay, Mariachiara Tallachini aims to overcome the property/privacy dichotomy in the regulation of human tissue. The author explores the main existing legal framing of biological materials, both in the US and the EU contexts, and the potential for reconciling individual and collective dimensions in biobanking

through a participatory approach. She draws an intriguing comparison between the regulation of human tissue and the environment, showing that the notions of both the subject of rights (the rights holder) and the object of property (the object held) have failed to fully represent the potential of collective sharing.

In his essay, Amedeo Santosuosso addresses the provocative question of whether privacy should be abolished in genetics and biobanking. Starting from a meticulous analysis of the interests at stake on the genetic information, he reaches the conclusion that the answer could be twofold: “The answer is yes, if privacy claims to extend biologically to any (even smaller and less significant) biological connection at any time. The answer is no, if privacy refers to people directly involved, their free determination and, in a wider area, only to those who have, or are able to, demonstrate a concrete interest, provided that public interest to the “common genetic railway” is properly stewarded”.

The contribution of Paolo Guarda aims to analyse the interaction between research biobanks and the Electronic Health Records (EHR) systems. The interaction between these two technological tools represents a step toward the definitive breach of the wall between clinical medicine and research, and it is one of the key points in order to build a process of personalised medicine. From the legal point of view, this interaction changes the role of the patient and, as remarked by the Author, “allows us to ‘spotlight’ the patient as both the person from whom tissue samples are collected and managed within the biobanks and also as a main character in the informational flow that must return to him as the result of the analysis undertaken by biobank research”.

The last article of the first part of the book, presented by Matteo Macilotti, dealt with the issue of informed consent in biobanking. In this contribution, the Author tries to overcome the debate about the possibility or impossibility of configuring a broad consent in biobanking, through the study of the legal status of human tissue. In particular, Macilotti proposes to modulate the level of information given to the patient on the specific interests that are recognised on the human tissue. Therefore, the main issue shifts from the acceptability of the broad consent to the proof of whether the information provided are sufficient to permit to the patient to protect his interests.

The second part of the book is devoted to the analysis of the issues related to intellectual property in the biobanking context. This topic is particularly complex and involves numerous stages of the biobank activity, the access to the resources collected in the biobanks (both tissue and data); the sharing of the data obtained through the analysis of tissue and the related information; the database protection, the patents developed, thanks to the tissue stored in a biobank, and the certification of the biobanks.

In the first contribution of the second part, Donna M. Gitter examines several challenges to widespread application of open-source principles to biobanks. In particular, she analyses the “reluctance among researchers to share their data; the challenge of crafting appropriate publication and intellectual property policies; the difficulties in affording informed consent, privacy, and confidentiality to research participants when data is shared very widely; controversy surrounding the issues of

commercialisation and benefit-sharing; and the complexity of establishing a suitable infrastructure". Her study is not limited to open-source model, but she proposes an alternative approach towards biobanks, the "fair access" model.

In a different perspective, the same topic is discussed in the essay written by Richard Gold and Dianne Nicol. Starting from the observation that in the last decade, the costs of drug discovery have grown exponentially while innovation has at best remained stable, or, at worst, in decline, the Authors recognise that collaborations and data sharing could offer important tools to rationalise the cost in time and money of drug discovery. Gold and Nicol carefully examine two models of collaboration through biobanks: open-access and open-source biobanks. Although the Authors highlight the problems that characterise each of these models, they reach the conclusion that, "where there exists a clearly defined community in which norm development and enforcement is possible, open-access would seem to be the preferred route. Where this feature is missing—the community may be too large and heterogeneous, there may be resistance to the use of norms and guidelines, or there may be a lack of leadership within the community—open-source may be the better option".

In the third contribution, Roberto Caso and Rossana Ducato dealt with the same general topic discussed in the two former contributions, but they pay more attention to the concrete biobanks governance. Biobanks are considered here not only as a provider of tissue and data but also as "data-centre" that collect the data derived from the researches conducted on tissue. Firstly, the Authors examine how IP, technology, social norm, and contracts interact in the specific context of data sharing in research biobanks. Secondly, they analyse the reasons why researchers should share the information with others, emphasising the crucial role of the contract as legal tool to encourage the researchers to share data with each other.

The contract represents the focus of the Thomas Margoni contribution. He analyses the role that Material Transfer Agreement (MTA) has accrued in the exchange of bio-materials between research institutions. Starting from the importance which MTAs have acquired in the most recent years, the Author remarks how an uncontrolled proliferation of MTAs could bring about a highly inefficient market situation. Showing how standardisation could partially fix these problems connected to the exchange of bio-materials and bio-samples, Margoni stresses on the importance of foreseeing a minimum level of flexibility in order to catch the huge varieties of situations involved. Finally, Margoni observes how new digital and web-based technologies can contribute in achieving such trade-off between standardisation and flexibility.

Going one step further, Michael Mattioli and Gideon Parchomovsky describe two new models for managing patents, raw data, and research findings at biobanks: quasi-patents and semi-patents. Quasi-patents are patents which can only be enforced against one's competitors and are a specially-tailored type of traditional patent that respect the importance of basic research. Differently, in the semi-patents model, researchers would be free to assert their patents against whoever they wish, but their right to exclude would be contingent on cooperation, with a mandatory data sharing policy. As highlighted by the Authors, both models can be understood

“as reconfigurations of property’s fundamental components: quasi-patents represent a shift of dominion, while semi-patents involve a splitting of the asset combined with new rules of acquisition and retention”.

The contribution proposed by Mark Perry offers an early study on a variety of practise of biobanks with regard to accessibility of materials and data, and the types of their collection. The study takes into consideration both human and non-human biobanks. While human biobanks are more regulated, with regard to the non-human biobanks, Perry observes a great divergence between how biobanks manage their material accessions, whether it is a physical sample use or even access to the data.

In the last article of the second part, Matteo Ferrari examines an unusual but crucial topic that has profound practical impact on the regulation of biobanking, the certification. After a description of the notion of certification, the Author tries to provide a taxonomy in terms of functions and types of certification and offers an analysis on how certification bodies can be rendered accountable for the service they provide. Afterwards, Ferrari focuses his attention on the biobanks’ context, adapting the general features of certifications described so far to the peculiar aspects characterising biobanks. Finally, he explores some of the possible benefits and problems that certifications can generate for the biobank domain.

The last part of the book presents three contributions by scientists who are involved as operators in the real world of biobanking.

The first one, by Mattia Barbareschi and his collaborators, focuses the attention on the workflow and organisation of a specific type of biobank, the tumour biobank. The analysis is based on the experience developed in the recently established Trentino Biobank (TBB), one of the most developed Italian biobanks based in Trentino Autonomous Province.

Moving from the Italian context to the European scenario, Giuliano D’Agnolo and Elena Bravo examine the Italian prototype networks of research biobanks. In particular, they give a report of the Italian participation to the Biobanking and Biomolecular Research Infrastructure (BBMRI), a European network that aims to harmonise standards for sample collection, storage, and analysis; to harmonise data collection and database infrastructure; to provide ethical and legal guidance; and to develop a sustainable funding model for biobanks.

In the third and last contribution, Barbara Parodi, Paola Visconti, Tiziana Ruzzon, and Mauro Truini dealt with the complex issue of the governance of biobanks for cancer research and they propose a peculiar model of material transfer agreement. Authors base their report on the experience gained, thanks to the IST Biological Resource Centre experience.

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