CHAPTER 10
FROM PRIVATE TO PUBLIC?

Legal Concepts of the Right to Privacy and Ownership in the Regulation of Biobanks

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I. INTRODUCTION

This chapter will examine the two main pillars of the legal norms related to biobanks: the right to privacy and the question of ownership. While privacy aims to restrict the access to biological samples and data, ownership is conceived increasingly as the right to their public use. In this paper we will explore the relationship between these two fundamental legal concepts in the context of contemporary biobanks since a comparative analysis of the two notions can bring more to the debate than their separate assessment.

The right to privacy in biobank regulations refers mainly to the protection of personal data in collecting, storing and processing samples and data, as well as the techniques of shielding data from the curious eyes of third parties. The right to privacy is intensively regulated as this is the most evident legal aspect of the biobank. Most international norms and national laws focus on protecting the data subject while claiming enhanced guarantees for securing privacy and confidentiality in the domain of biobanks. Some authors, such as Graeme Laurie (2002), have already elaborated a special privacy concept: the notion of genetic privacy that can be already discovered in legal instruments.

Contrary to privacy issues, ownership constitutes a hidden but lingering legal problem. Ownership of the human body and its parts is generally rejected in European legal systems, and among the various laws on biobanks, only a few dare to address this question in a detailed fashion. Because of this uncertainty, laws often remain silent or ambiguous on the ownership of tissues and biobanks or at least try to avoid a clear interpretation of this problem.

At first it would appear that the two legal concepts refer to two separate components of biobanking: privacy is related to genetic and biomedical data,
while ownership is used in connection with the physical sample. It also seems that a kind of *quid pro quo* approach can be observed: while personal privacy in data banking affirms the position of the data subject, the notion of public access and the prohibition of financial gain (at least by the donor of the sample) weakens the position of the donors of the biobank.

However, in a closer analysis one may see that the two concepts have many overlapping interpretations. The right to privacy can serve as an important tool for the protection of physical samples as well. Further, in order to grant ownership and access to some information on the findings of biobank-related research, privacy serves as a fundamental precondition. Moreover, the parallel analysis of the two concepts can help to capture the dynamic development of the biobank from passive collection to an active research tool.

II. RIGHT TO PRIVACY

The legal concept of the right to privacy provides a theoretical foundation to guarantee various forms of self-determination over the human body. However, when the issue of disconnected body parts, human tissues and DNA is raised, the concept of privacy seems to be an insufficient legal category to describe the complex relationship between the donor and the stored human tissue samples that are used for research purposes. On the one hand, the human DNA sample symbolizes and represents the person, but on the other hand it is also regarded as a gift, a personal contribution to research of public interest and a symbol of public participation.

Even if, literally speaking, the ‘right to privacy’ is not mentioned in many European Constitutions, the concept, as well as its specific elements, are well known. Although there is no unanimous interpretation on the right to privacy, the concept of ‘respect to private life’ is used by many legal scholars.

Since World War II, rights within the health care domain are increasingly regarded as universal human rights. Furthermore, legal guarantees of research performed on human beings have been a significant part of medical ethics and bioethics. For instance, the legal principle that no one shall be subject to research without his/her express consent arises from the basic right to human dignity. Furthermore, the interests of the individual prevail over scientific interests even in the most important fields of biomedical research. In the Oviedo Convention, privacy was elaborated even further.

It follows from Article 10 of the Oviedo Convention that everyone can decide whether or not to be informed of the results of genetic examination and the ensuing consequences should be respected. At the international level, an influential though not binding instrument, the UNESCO Declaration on Human Genome and Human Rights states in Article 5 that “the rights of every individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.”

Further guarantees for privacy are stated in the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes. Article 9 asserts that “(1) A genetic test may only be carried out after the person concerned has given free and informed consent to it. Consent to tests referred to in Article 8, paragraph 2, shall be documented. (2) The person concerned may freely withdraw consent at any time.” Interestingly, this principle is rarely formulated in such a strong way in biobank regulations.

Similarly, if one examines the most recent national legal norms on biobanks, it is evident that privacy and data protection constitute key legislative elements. In addition to general provisions on the right to privacy in biomedical research, recent laws on biobanks provide additional guarantees to the right to privacy. For instance, during the debates on the Hungarian Bill on Genetic data and biobanks it was later approved as the Parliamentary Act No. XXI of 2008 on the Protection of human genetic data and the regulation of human genetic studies, research and biobanks’ – concerns for privacy were so strong that a special category of coding were included in the law. This was termed the *pseudonym genetic sample or data* – meaning encoded genetic sample or data, regarding which, the code replacing the personal identification data was provided to the person concerned.

Another example is the Spanish Law No. 14 of 2007 on Biomedical Research, which dedicates a special title for biobanks. In this title Article 45 (b) refers to privacy as “the right to privacy and to the respect of the will of a subject shall be guaranteed in matters of information, as well as the confidentiality of genetic data of a personal nature.”

III. ‘BODY IN BANK’

Confusion and problems with regulating privacy and ownership has accelerated with the tissue hunger of the biotech industry. During the last fifty years the scope of medical research has expanded significantly and the rules regulating such research have multiplied. At the beginning of the 21st century, not only human beings, but also animals used in research are granted more protection than ever before. However, one of the most significant recent developments is that now a major part of the research is implemented months or even years after the patient received medical treatment and gave a DNA sample. In the era of biobanks, it is also increasingly frequent that someone in perfect health would voluntarily provide a blood sample to a biological sample collection. Organ and
tissues removed from deceased persons were formerly classified as hazardous waste, but today these are considered precious material for research conducted even long after death. The unprecedented increase in the establishment of biobanks not only changed the scope of scientific studies on human beings but also stimulated more lively interest among the wider public in research performed on human biological samples. Not only the rules of giving consent but also data protection has improved greatly during the past twenty years.

The increasing use of human tissues extends the scope of ethical dilemmas arising from moral rights and concerning the right of disposal of one's body. The issue of interpreting human dignity in another context is raised, i.e. the purpose of protecting personality should be before the legislator's eyes not only directly, during the treatment, but also when using the information obtained from human tissues or any fact or conclusion related to the individual.

Today a DNA sample of a rare or serious disease together with the health record of the patient can serve as a basis for research and also hold out promises of considerable financial benefits (Franceschi 2004). Nevertheless, the person providing the sample may not in fact receive a share of such financial benefits directly. Moreover, that person usually does not have therapeutic benefit from providing a sample at all.

The decreasing reaction time between the occurrence of a new technology and its regulation results in a regulatory race and an inflation of often conflicting regulations. It may be observed, especially in the standard setting work of various professional bodies, that new legal terms are introduced in a way that they overlap with or even contradict previously used terminologies. As mentioned above, biobanks may be defined in diverse ways; even such legal terms as an identified or identifiable data are used in many different ways. Hasty law making and the proliferation of elusive new terms have created a great ambiguity among researchers and policy makers alike in their effort to apply legal frameworks to biobanks. Further, this lack of clarity characterizes not only national laws but international legal instruments as well.

In the field of the rapidly expanding legal framework, word by word interpretation is often not helpful, as even the titles of new legal norms may appear confusing. For instance, the Tissue Directive of the European Union is not about tissue biobanks – in the sense that it does not cover biobanks that are established for research purposes. Furthermore, although, biologically, blood is regarded as a human tissue, it does not fall under the scope of the Directive except in the form of haematopoietic peripheral blood and umbilical-cord blood. The regulation on advanced therapies does cover tissue engineering. In addition, biobank laws sometimes use the term 'donor' which may also be misleading as the donation of an organ and tissue for transplantation fall under an entirely different legal framework from the donation of cells and tissues for biobank. Rules are different in case of organ donation, which is characterized by altruism, and usually anonymity is secured (except for donation among relatives). Sometimes tissues are governed by a different legal framework than cells but not in all contexts and some scholars try to argue further that human rights regulation on body parts does not cover human tissues.

Another example for the frequent misunderstandings is Article 21 of the Oviedo Convention, which states that "The human body and its parts shall not, as such, give rise to financial gain." This phrasing, in itself, leaves the question as to whether a tissue or a cell of the human body constitutes a part of the body, open to interpretation. However, Paragraph 132 of the Explanatory Report on the Oviedo Convention solves this ambiguity by including tissues among the parts of the body that cannot be commodified: "Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital" (Council of Europe 1996). According to this interpretation only so-called 'discarded parts' of the body fell outside the scope of the Convention, such as hair and nails.

The Explanatory Report is also very useful in drawing a distinction between raw human tissues and technical acts such as sampling, testing, pasteurization, fractionation, purification, storage, culture, transport, etc. which are performed on the basis of these items and that may legitimately give rise to reasonable remuneration.

Furthermore, while Article 21 of the Oviedo Convention does not allow a person from whom an organ or tissue has been removed to accept financial remuneration, it does not prevent that person from receiving equitable compensation for expenses incurred or loss of income (for example as a result of hospitalization).

Regulations of biobanks in most cases do not cover all kinds of collections of biological specimens: forensic databases operate under entirely different legal frameworks, registries still coexist in the domain of medical law, etc. Surveying the variety of logical divisions among various kinds of regulation, it is no wonder that a social science and legal researcher of biobanks encounter enormous confusion in the science sector. Some biobank directors believe that their activity falls under the transplantation laws of their respective countries, whereas certain others simply extend the scope of the Tissue Directive and apply the same rules for clinical and in vitro research. In 2006, a publication written for the Medical Research Council and the Wellcome Trust stated that "Many academic scientists express confusion, if not consternation, over the meaning and practical implications of possession, custodianship, ownership, database rights and intellectual property (IP) generally. Some do not understand their roles in
between the university and the founders, and some complain that they hear differing explanations from the two sides. Some are unsure as to whether materials have different IP status from data. All of this is pertinent to the sharing of data and materials..." (Lowrence 2006, 26).

As discussed, the right to privacy is especially important in the field of genetic research and human biobanks because given the lack of a clear arrangement on ownership rights, privacy is the only tool in the hand of the individual that can still provide control both in cases of public access, as well in cases of private commercialization.

IV. OWNERSHIP

Ownership of samples constitutes the other important question related to biobanks with serious implications for commercialization. Ownership in itself constitutes a complex set of questions, such as who is the owner of the biobank, who can get access to the samples or whether samples can be used for making profitable invention. Among other authors, Boggio (2008) emphasizes that ownership rights regarding genetic material are controversial. Jasper A. Bovenberg (2006, 2) differentiates between various forms of property in relation to DNA such as academic property, universal property, personal property, intellectual property and taxable property. Concepts such as biowaste, biogift, biocapital (Walby and Mitchell 2006) all refer to fundamentally different legal implications of the human tissues separated from the human body.

Recommendation Rec (2006) 4 of the of the Committee of Ministers to member states on research on biological materials of human origin reinforces the "prohibition of financial gain" expressed in the Oviedo Convention by stating in its Article 7 that "Biological materials should not, as such, give rise to financial gain."

While the Convention on Human Rights and Biomedicine of the Council of Europe includes the provision that the human body and its parts shall not give rise to financial gain, this Article does not appear to cover the data derived from the physical samples. In practice, data may be an asset of an even higher commercial value than the samples themselves.

But even if a law regulates ownership of samples and access to data it is usually concerned with the consequences of and the duties related to ownership rather than with the covering of all kinds of sample-data scenario. For instance, according to Article 65 of the Spanish law on biomedical research, "The physical or legal person, public or private, that holds ownership of a biobank shall be responsible for it. (2) If there is a change in the ownership of the person responsible for the biobank, or the modification or broadening of the objectives of it, then that event shall be communicated to the corresponding authority, who, where appropriate, shall grant a new authorization."

The legal debates on privacy and ownership are not new in the biomedical context. One of the first internationally known legal debates on the benefit received from the use of human tissues was already discussed in the American Moore case (Moore v. Regents of the University of California).

John Moore had hairy cell leukemia and, following his father's advice, he underwent treatment at the clinic of a prestigious university, the Los Angeles University Hospital, between 1976 and 1983. His disease was successfully treated by Dr. David Golde, leader of the hospital medical team. Along with the treatment, however, the doctor made important studies on the patient's tissue samples. The patient's spleen had to be removed in the course of the series of treatments but many times blood, sperm, bone-marrow and other biological samples were also taken from the patient for the purpose of examination. Since Moore was satisfied with the medical care, he traveled from Seattle to Los Angeles for treatment for many years.

John Moore began to become suspicious only when in 1983, seven years after the commencement of the treatments, he had to fill a statement of consent, stating that he voluntarily consented to transfer all his rights over his cell lines and other biological samples to the university. He marked the sentence "I do not consent to it" with a circle. Since the clinic thereafter phoned him and asked him to change his opinion, seeing the great excitement about his tissues, Moore turned to a lawyer. His lawyer found a patent concerning a cell line called "Mo" which produced a large profit for the research team. Then Moore announced a claim for sharing the profit resulted from the biotechnological invention, stating that it was based upon his biological samples. The court refused to accept this pecuniary claim but established that the doctor's conduct, i.e. non-disclosure of research and business interests to the patient, should be considered as an infringement of the relationship of trust between doctor and patient (breach of the so-called fiduciary duties). In other words; while ownership over his cells and tissues were not granted to Moore, his privacy rights to know what would happen to his tissues and cells and why were acknowledged.

Returning to the use of human biological samples for trade purposes, what if the invention based on human tissues is not created secretly but with the express consent or moreover with the intellectual or financial support of the subject participating in the project and providing the sample? Should the donor be considered as a voluntary provider of the sample in this case too?

Patients' groups often participate in biomedical research by providing, besides their tissue samples, significant financial and recruitment support for research. One example is the organizations of the parents of children suffering from Canavan disease who participated in its research with great dedication.
and intensity: they not only organized the gathering of samples but also supported researchers with significant financial resources so they could create genetic tests as soon as possible. Groups of relevant patients and non-profit organizations offered their help in the research activities concerning Canavan disease (Weir and Olick 2004, 164). They not only provided their own tissue samples for the research but also contributed to it financially. As a result of the research supported in this way a patented invention was created, which could be obtained for payment even by the contributing patients themselves. Therefore the patients’ group initiated a lawsuit in October 2000. The Court of Florida acting in the case confirmed the former court decision adopted in the Moore case, and refused to recognize the plaintiffs’ claim to title.

It seems to be unfair that researchers and biotech companies may have a significant financial benefit due to a biotechnological patent but the most affected person, i.e. the patient, obtains nothing from the benefits of the research, especially if he can purchase the test, medicine or procedure created due to the invention only for a lot of money later on. However, research would be almost impossible if donors had previously entered into complicated negotiations with the relevant research team. Although there are international research teams that voluntarily include a so-called profit-sharing clause in the research agreement, or ensure a partner relationship through individual agreements with the donors participating in the research and providing samples, it has not been a uniform approach so far.

Still, many laws related to biobanks have expressly engaged with the concept of prohibition of financial gain. The Spanish law refers to it as principle of ‘gratuity’ which means that "all the process of donation, assignment, storage and use of biological samples, both for the source subjects as well as for those who deposit, shall be devoid of a financial gain or profit. Personal genetic data shall not be used for commercial purposes."15

For the time being, the question is still open on how human tissues should be considered if they serve the purpose of creating valuable biological inventions in biobanks or via international cooperation, i.e. should they be considered as a contribution in kind or a common heritage?

Currently there appear to be three solutions in this field. The first one is the creation of an open market, which is so far inconsistent with the approach of European law44 and really has dangerous consequences. This would be the case when research subjects, organ donors, DNA and other donors provided samples for money or other direct financial benefits.

The second solution may be a form of symbolic reimbursement that does not involve any direct financial benefit. It can be expressed as the provision of free genetic tests, medical treatment or medicine at a reduced price for the persons participating in the creation of the relevant biotechnological or pharmaceutical product. It can also take the form of health benefits providing for early diagnosis or prevention.

The third solution is the development of a new kind of ownership construction, such as the one based on an extension of the concept of common heritage. There are several arguments in support of public ownership, too – in the event of an epidemic, for example, all virus samples belong to the public. If the virus sample is not provided immediately and for free but only after protracted negotiations, it might entail consequences that are difficult to foresee.

With the sale and purchase of biological samples the danger of bioterrorism may also increase. Hunting for specific disease traits may also alter the situation of some patients’ groups.

Human DNA may be considered as some kind of common heritage of mankind. The concept of mankind’s common heritage, as well as the specific ownership category thereof, was inspired by environmental protection. As is widely known, Mr. Arvid Pardo, Ambassador of Malta made first official mention of this in 1967 in his address to the United Nations General Assembly, and this concept has served as a model since then for everyone keeping the protection of future generations in mind. However, Arvid Pardo’s famous sentences at that time referred to the treasures of the ocean only.

This communitarian concept related to the human genome came up in 1997 when the Universal Declaration on the Human Genome and Human Rights was adopted by the General Assembly of UNESCO. Under Article 1 of this Declaration “the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.” It is not accidental that ownership disputes became more and more conspicuous after the escalation of genetic research. The genes that can be studied independently from the body include hereditary traits which may reveal information that have not only scientific and therapeutic but also social and cultural meanings. If it comes to legislation we find that the legislator has to cope with both the real possibilities of science and the risks to human rights arising from it, as well as the prejudices and fears that surround genetic research while not necessarily resulting from the scientifically verifiable achievements of genetics themselves.

Whatever the solution will be, we should see that the increasing use of DNA samples and biological tissue samples for research and biotechnological purposes confronted not only the researchers with a new situation but radically rearranged the legal issues and, last but not least, the research subjects’ (today preferably called ‘participants’) attitude to the research. According to David Price (2000), biological interpersonal relations are increasing more intensively today than ever before. Citizens get in contact with each other not only through services and the labor market but they are also connected to each other with more and more
biological strings. Since it seems that the mapping of human genome and the research arising from it are hopefully to everyone's advantage, the organs offered for transplantation, biobanks, stem cells and umbilical cord blood are all important primary materials and elements of diagnosis and therapy. Although the Human Genome Project did not apply the benefit sharing approach, it has engaged with the common heritage discourse. And the legal concept of benefit sharing dates back even to the Rio Convention on Biodiversity.

The term biobank itself already refers to a more commercialized relationship that is based on a quid pro quo connection between the donor and the owners of the biobank. This perspective seems to be inconsistent with the approach of European law (especially with the Oviedo Convention) and one does not have to apply a slippery slope argument to see much broader consequences of such commercialization. This would be the case when research subjects, organ donors, or DNA donors provided samples for money or other direct financial benefits. Furthermore, if research falls under the direct influence of trade, this might spill over to affect other fields – for example, considerations of solidarity and altruism might disappear in cases of transplantation or stem cell banks would operate only as so-called autologous banks, that is, banks established exclusively for the participants' own purposes.

A less commercialized solution would be when the benefit of or reimbursement for providing samples is more symbolic and does not imply any direct financial benefit. It can be expressed in the form of offering free genetic tests, medical treatment or medicine at a reduced price for the persons participating in the creation of the relevant biotechnological or pharmaceutical product.

In the case of biobanks neither the common heritage approach nor the principle of benefit sharing seems to be a guiding idea. This is so even if some patient and family groups may be unwilling to donate their samples to biobanks unless they have a right to access the final products and the patents (Robertson 2003).

V. CONCLUSIONS

As we saw, the two pillars of biobank regulations, privacy and ownership, are strongly linked to one another. Privacy often serves as theoretical foundation of other rights. While individual privacy should be secured and requires enhanced methods and detailed by-laws of biobanks, exclusive ownership on samples and on the biobank itself would constitute legal hazards. Biobank regulation should carefully balance between these two interests and free gift should no longer be presumed especially in cases of massive expropriation of samples by researchers and industry. Biobanks would better build on a regulated trust relationship where right to privacy would protect the interests of the biobank research subject, regulated access to samples would provide opportunity for researchers and custodial rights of the managers of the biobanks would define their legal relationship to biobanks. As a research subject can withdraw samples and data instead of ownership, custodial rights would better describe the rights and duties of the owners of the biobank. Regardless of its public or private funding, biobanks constitute a public enterprise in the sense of including some waiver of individual rights in order to grant research for public benefit.

LITERATURE


Moore v. Regents of the University of California, 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479, 501 (1990)


1. In this short study I intend to avoid the discussion of the notion and scope of biobanks. Even within Europe, biobanks have been defined in quite diverse ways. In the joint opinion of the French-German National Ethics Committee, for example, biobanks are defined as "privately or publicly maintained bodies for the long-term storage of human bodily substances." In the Swedish law biobank is understood as "Biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates." In the Hungarian law "Biobank means the collection of samples containing genetic samples and related genetic and personal identification data for the purposes of a human genetic study or human genetic research."

2. Article 2 of the Oviedo Convention: "The interests and welfare of the human being shall prevail over the sole interest of society or science."

3. This Act entered into force on 1 July 2008.


5. Since the establishment of the first biological sample collections for epidemiologic purposes, after the Human Genome Programme, there were thousands of biological sample collections and DNA banks established worldwide in the hope of serious research and trade possibilities.


7. Recital 11 of the Tissue Directive states that "This Directive does not cover research using human tissues and cells for instance when used for purposes other than application to the human body, e.g. in vitro research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive."

8. Recital 7 of the Tissue Directive states that "This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells."


10. Here he refers to the ruling of the Canavan case (Greenberg v. Miami Children's Hospital); more on this see also Weir and Olick (2004).