Chapter 7
Should Privacy Be Abolished in Genetics and Biobanking?

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Abstract In this paper, after a short outline of current main features of biobanking, first the disenchantment on privacy and informed consent in the field is presented and discussed as a reaction to the recognition of full (individual) rights even to each piece of biological materials and/or genetic information. Secondly, the real interests at stake (when biological materials and genetic information are involved) are clarified: is human genome really/exclusively human? What are the boundaries of human family and those of biological group? What does biological group encompass in scientific terms and legal terms? Under what conditions and to what extent does the individual compass interact with those of other family members and with the biological group as a whole? Finally, both the human individual and the biological group compass are conceptualized as legal artefacts, whose definitions are the responsibility of lawmakers and individuals and not of scientists, even if lawmakers and individuals should act being fully aware of the latest scientific findings and views.

7.1 Individual Privacy and Family Ties in Genetics and Biobanking

The concept of privacy has expanded as innovations in technology have made public what was previously out of the public view. Initially, it was photographs and newspapers that "invaded the sacred precincts of private and domestic life" (Warren and Brandeis 1890). In recent decades, other developments have further enriched the concept of privacy. Indeed, because of the extraordinary development of biological sciences and medicine, the right to privacy has taken the shape of right

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to self-determination in choices regarding individual life and medical treatments (such as the use of contraceptives, abortion, and end-of-life decisions). On the other hand, informational privacy has stemmed from information technologies, which have made it possible to collect, store, and access huge quantities of data (including medical and health data) on individuals. Since human genetic information is often viewed as a type of personal information that needs special protection,[1] questions on informational privacy include whether people have any right of ownership over their stored (genetic) information and whether they have a right to view, verify, and challenge that information.

In general terms, the individual's legal endowment has widened and gained new ground, as new aspects of a person's sensitivity, personality, ideas, and interests are perceived to be under threat and require legal protection.[2] A very recent EU document refers to the connected issue of personal data and states that, according to the current EU legislation, "the definition of 'personal data' aims at covering all information relating to an identified or identifiable person, either directly or indirectly".[3]

This individualistic approach has worked well in fields where the individual can be considered as an isolated entity, clearly distinct and independent from society. However, this approach leads to paradoxical consequences when mechanically applied to genetics. Assuming that biobanking is a fundamental tool in genetic research,[4] there are two main reasons that make the individualistic way of dealing with the issue unworkable: on one side, genetic data endure for the entire length of an individual's life and beyond; on the other, genetics is the domain of familiarity of heritable characteristics, and the individual is considered in all his/her biological connections with the other members of his/her family.

In this paper, after a short outline of current main features of biobanking, firstly, the disenchantment on privacy and informed consent in the field is presented and discussed as a reaction to the recognition of full (individual) rights even to each piece of biological materials and/or genetic information. Secondly, the real interests at stake (when biological materials and genetic information are involved) are clarified: is human genome really/exclusively human? What are the boundaries of human family and those of biological group? What does biological group

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[1] See Study on the Economic Benefits of Privacy Enhancing Technologies (PETs). Final Report to the European Commission (2010) and also UNESCO International Bioethics Committee. DRAFT International Declaration on human genetic data, Addendum 2, 8.10. 2003: "Human genetic data have a special status. Due consideration should be given and where appropriate special protection should be afforded to human genetic data and to biological samples".

[2] Among many others, a list of definitions is available at http://www.privileged.group.shef.ac.uk/. See also Article 29 Data Protection Working Party (2009).

[3] European Commission, Brussels, 4.11.2010, com(2010) 609 final, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, A comprehensive approach on personal data protection in the European Union.

[4] "Human biobanks and genetic research databases, which bring together and allow the sharing of human biological material and information derived from its analysis, are a key element of the scientific infrastructure underpinning such research" (OECD 2009).

encompass in scientific terms and legal terms? Under what conditions and to what extent does the individual compass interact with those of other family members and with the biological group as a whole? Finally, both the human individual and the biological group compass are conceptualised as legal artefacts, whose definitions are the responsibility of lawmakers and individuals and not of scientists, because even lawmakers and individuals must be fully aware of the latest scientific findings and views.

7.2 Current Main Features in Biobanking and Privacy

It is well known that the term biobank is relatively new, as "it appeared in PubMed for the first time in 1996 (Loft and Poulsen 1996) but was not used with any frequency until 2000. Although the term is used to describe various biological repositories, it originally referred to large population banks of human tissue and related data".[5]

Thus, it is clear that when talking of biobanks, a crucial point is that of how to define them, what items to include in their compass, and what kind of response to give to crucial issues such as confidentiality and access.

7.2.1 Definitions

A study funded by the European Union has listed about twenty-six definitions, while contributions are still open.[6] In very general terms, we can say that each definition depends on the aspect that he/she who gives the definition wants to stress. To give some examples, *human* biobanks emphasise that human materials are collected, rather than materials of vegetal or animal origin; a *gene* bank means "a database established and maintained by the chief processor consisting of tissue samples, descriptions of DNA, descriptions of state of health, genealogies, genetic data and data enabling the identification of gene donors"[7]; in the use of the word *repository* (instead of *bank*), there is a clear intention to escape the financial metaphor of bank towards a more neutral word/concept.

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[5] Elger and Caplan (2006).

[6] The Project (2007–2009) was coordinated by Mark Taylor (Sheffield Institute of Biotechnological Law and Ethics, School of Law, University of Sheffield) and David Townend (Faculty of Health, Medicine and Life Sciences, Department of Health, Ethics & Society, Maastricht University) and was looking to determine the ethical and legal interests in privacy and data protection for research involving the use of genetic databases and biobanks. Please find the list at http://www.privileged.group.shef.ac.uk/. Accessed 30 October 2010.

[7] According to the Estonian Human Genes Research Act, 2000, as reported at http://www.privileged.group.shef.ac.uk/. Accessed 30 October 2010.

Currently, there is enormous variation in the definitions used in regulatory literature: “Some literature refers explicitly to biobanks, such as the Norwegian law in which the definition includes samples without explicit reference to data, i.e. a biobank is a collection of biological samples which are permanently preserved. Others include a gene bank (Estonia), a database of gene donors (Latvia) or several kinds of biobanks (diagnostic/research)”.[8]

Although the word biobank frequently refers to “any collection of human biological material—organs, tissue, blood, cells and other body fluids—that contains at least traces of DNA or RNA that would allow genetic analysis”,[9] it is well known that biobanks have a twofold character, as they can collect samples or data or both samples and data. However, it is becoming increasingly necessary to distinguish between *data* biobanks as opposed to *sample/tissue* biobanks, according to what they store (biological materials or—simply—data originating from some biological material). [10]

Of course, in this way, further material-centred kinds of *samples/tissue* biobanks can be listed, such as *Umbilical Cord* biobanks, *Cancer Human* biobanks,[11] *Stem Cell* biobanks, *Synthetic Biology* biobanks, and so on. A study conducted in the EU shows that, “most biobanks store DNA combined with serum, whole blood and/or different types of tissue, whereas only 12 % store DNA alone. Other tissues stored (as specified by the respondents) include, for example, stem cells and RNA, urine, dried blood and red blood cells”.[12]

Further distinctions are based on the purpose of the repository: *diagnostic* biobanks, *disease-oriented* biobanks, *research* biobanks, *police* biobanks and more.

Of course, each of the above-listed definitions does not necessarily exclude the others, as, for instance, a research biobank may also be, at the same time, a sample biobank and a disease biobank and a stem cell biobank and more. Nevertheless, some distinctions have a greater importance as they are linked to socially sensitive points. A clear example is the distinction between *police* biobanks, whose materials are collected independently of the consent of involved people (being such biobanks established for criminal investigation purposes), and *research* biobanks, whose

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[8] Cambon-Thomsen et al. (2007).

[9] Elger and Caplan (2006).

[10] Nationaler Ethikrat defines biobanks as collections of samples of human body substances (e.g. tissue, blood, DNA), which are electronically linked to personal data and in particular to health information on the donors (Nationaler Ethikrat 2004).

[11] “In response to a critical and growing shortage of high-quality, well-documented human biospecimens for cancer research, the National Cancer Institute is developing a national, standardized human biospecimen resource called the cancer Human Biobank (caHUB). Currently, no centralized, standardized infrastructure of this type exists in the United States. caHUB will serve as a continuous and reliable source of high-quality human biospecimens and associated data for the broader cancer community, including basic and clinical researchers and the biotechnology and pharmaceutical industries that rely on human biospecimens for cancer diagnostics and drug development”. http://biospecimens.cancer.gov/cahub/default.asp. Accessed 30 October 2010.

[12] Zika et al. (2010).

materials are fundamentally collected on a confidential basis and with the consent of involved people.

7.2.2 Interconnection of Biobanks, Confidentiality and Access

Needless to say that confidentiality is a critical point and is likely to become even more critical if we consider the move towards interconnection between biobanks and the possibility of multiple accesses to them. A study promoted by the EU Commission exactly focuses on harmonisation and interconnection of existing biobanks: “While biobanks are increasingly recognised as a crucial infrastructure for research, at the same time the widely varied practices in biobanking regarding for example collection, storage and consent procedures may also pose a barrier to cross-border research and collaboration by limiting access to samples and data. In this context, a recent study indicates that the limited sharing and linkage of samples is a key barrier for research, such as pharmacogenetics. Wide variation is observed in the implementation of relevant existing regulation, which may add further burden to harnessing the public health benefit of these collections. Therefore, it has been suggested that there is a strong need for a harmonised approach on biobanking practices and improved networking of existing and new collections”.[13]

What is worth noting is that, if the need that “research must respect the participants and be conducted in ways that uphold human dignity, fundamental freedoms and human rights” is universally shared,[14] the passage move from isolated biobanks to networked biobanks implies a scale shift of old (still unresolved) problems. For instance, even traditional distinctions (such as that between *police* and *research* biobanks) that were supposed to be strong because of the kind of stored materials and the rules of collection (voluntariness, previous information) and access, seems to become uncertain. Indeed, even bio samples and DNA profiles collected in police laboratories, repositories and databases might be an interesting source of information for scientific research, e.g. research on responsibility, behavioural genetics, psychiatry, neuroscience and more. On the other hand (and most significantly), even research biobanks can be searched by police and the more connected they are, the more appealing they might be for investigative purposes.

The problem with the interconnection between databases for criminal investigation purposes and research biobanks is the possibility of multiple accesses by the police with or without a Court order. As said above, the word biobank encompasses many different realities and entities and differs according to the kind of materials

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[13] The Institute for Prospective Technological Studies (IPTS) of the European Commission’s Joint Research Centre, in collaboration with the European Science and Technology Observatory (ESTO), launched the following study: Zika et al. (2010). See also Scaffardi (2008).

[14] See, e.g., *Guidelines for human biobanks, genetic research databases and associated data*, prepared by the Office of Population Health Genomics Public Health Division, Government of West Australia, February 2010.

and information they collect. With the exception of police biobanks, all others collect materials on a confidential and voluntary basis and give guarantees of respect of informed consent as to the limits of use of the material and information.

The problem is whether the police could be interested in searching other biobanks. No case of this kind is currently reported, but we cannot exclude such an interest, either theoretically or practically. Otherwise, what might be the reason why the UK research database in 2005 inserted in its rules of access the possibility of police access, even if with a court order?[15] We also have to wonder why in 2004 the *Nationaler Ethikrat* of the Federal Republic of Germany (National Ethics Council, NER) and the French *Comité consultatif national d'éthique* (CCNE), in a jointly delivered opinion, stress the following point: "biobanks not only promise benefits, but also arouse anxiety and distrust within the community. These reactions are due to concern that the data and bodily substances might be used for purposes other than those to which donors have consented. For this reason, the samples and information accruing from a medical research project should not be made available to the police, the judicial authorities, employers or insurance companies".[16]

More recently, the OECD Guidelines on Human Biobanks and Genetic Research Databases (2009) states at point 7.F that, except when required by law, the operators of HBGRD should not make accessible or disclose participants' human biological materials or data to third parties (e.g. law enforcement agencies, employers, insurance providers for non-research purposes).

The issue is not considered at all in some relevant international[17] and national[18] documents, while in other more recent guidelines, it is carefully scrutinised. The Australian Office of Population Health Genomics, Public Health Division, published in February 2010 the *Guidelines for human biobanks, genetic research databases and associated data* that shows a high level of attention on the issue: "It is clear that wide access to such data for biomedical advances must be balanced by consideration of the interests of research participants. The ability to establish biobanks and genetic research databases will depend in part on research participants' willingness to contribute. Research must respect the participants and

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[15] UK Biobank (2005). The drafters take some precautions on this very crucial point and say: "It is likely that UK Biobank will take steps to resist access for police or forensic use, in particular by seeking to be represented in all court applications for access in order to defend participants' trust and public confidence in UK Biobank" (p. 5). The problem is if sample givers are informed about this possibility. In its latest version, the policy seems to be less restrictive "Access to the resource by the police or other law enforcement agencies will be acceded to only under court order, and UK Biobank will resist such access vigorously in all circumstances", UK Biobank (2007).

[16] The opinion *Biobanks for research* was published in 2004 by the German National Ethics Council (chair: Prof. Spiros Simitis), www.ethikrat.org, pp. 98–99.

[17] Such as International Declaration on Human Genetic Data (16 October 2003) and Recommendation of the Council of Europe Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin (adopted 15 March 2006).

[18] See Italian National Bioethics Committee (2006). Opinion of the NBC on a Recommendation of the Council of Europe and on a document of the National Committee for Biosecurity and Biotechnology (2006).

be conducted in ways that uphold human dignity, fundamental freedoms and human rights".[19]

At Chap. 7, the AU document is very detailed and recalls that, according to Australian legislation, law enforcement agencies may obtain access "if the Coroner reasonably believes it necessary for the investigation" and thus authorises a police officer "to enter a specific place, to inspect a specified place and anything in it, take a copy of specified documents or classes of documents and seize specified things or classes of things. It is an offence for the Department to delay, obstruct or otherwise hinder the exercise of the power to take documents with written authority". More specifically the Criminal Investigation Act 2006 (WA) states that, "if an individual dies as part of any offence under written law, then a search warrant, sought by a police officer (who is also a Coroner's investigator) or a public officer may be used to seek biological material and related information".

The Australian document has the merit of going into details of what could be considered evident in general terms, in any country. It is clear that the problem cannot be denied and any barrier erected in the name of confidentiality of the collection of samples is unfortunately extremely weak once criminal investigation needs are at stake. We have to realistically admit that, even without any specific legal provision allowing the police to have access, no judge or court would refuse to sign an order once police officers have given a reasonable demonstration of the utility of questioning a research biobank in a serious crime investigation. Also, an explicit legal prohibition of such access could probably be questioned from a constitutional point of view or in principle. Moreover, if this is true for investigation needs in serious crimes, there is no reason to exclude a similar access for severe public health reasons.

The most exhaustive discussion of the issue is presently in the Opinion on *Human Biobanks for Research* prepared by the *Deutscher Ethikrat* in 2010, pp. 33–34. They state that, "not only the research institutions which have established biobanks, but also third parties may be interested in using biobanks. This applies, for example, to insurance companies and employers, but also to state agencies, for example in connection with warding off danger and criminal prosecution and to identify victims of catastrophes or to establish identity in connection with litigation in the civil courts".[20]

The opinion surveys foreign experiences and recalls that such a use of biobanks has already occurred in Sweden, where the nationwide PKU biobank, which since 1975 has collected DNA from every newborn in order to research the metabolic disease phenylketonuria (PKU), was used in 2003 in order to convict the murderer of the Swedish foreign minister Anna Lindh, and later to identify victims of the

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[19] Office of Population Health Genomics, Public Health Division, Guidelines for human biobanks, genetic research databases and associated data (February 2010), p. iii, at http://www.genomics.health.wa.gov.au/publications/docs/guidelines_for_human_biobanks.pdf.

[20] German Ethics Council (2010).

December 2004 tsunami.[21] Then they clearly recognise (showing a more realistic approach than in the previous 2004 Opinion) that, "in Germany too, it is in principle possible for the security services to access biobank samples and data. It may be assumed that the interest of private and state agencies in using systematically designed and informative biobanks will increase. Such access raises central questions as to rights of personality and data protection (p. 14)".

Dealing with biobank secrecy and the need for protection, they note that, although there are "no specific provisions for biobanks", there are "models for this in current law" that can be used, and suggest that, "there must also be provisions defining the right to refuse to give evidence for persons with a duty of professional discretion [comparable to section 53 of the *Strafprozessordnung* (Code of Criminal Procedure)] which prevents these persons from having to testify as witnesses and thus break their duty of professional discretion to a state agency" (p. 28).

The main points are as follows (pp. 28–34):

- "Donors who provide samples and data disclose extensive and sometimes sensitive information on their person and therefore deserve particular protection of their rights of personality";
- "at the same time, the constitutionally guaranteed freedom of research under Article 5(3) of the Basic Law suggests that data traffic within the domain of research should be given particular privileges and should be separated from other (non-academic) domains. [. . .] all persons who have de facto access to data keys and identifying data should be included in the group of persons with a duty of biobank secrecy";
- "biobank secrecy should include a right to refuse to give evidence and a prohibition of seizure";
- thus, "if the legislature created a right to refuse to give evidence for persons who deal with biobank materials and data, it would also be complying with its particular mandate of protection of personal data. [. . .] The right to refuse to give evidence is justified for the protection of the general right of personality and the right to informational self-determination under Article 1 in conjunction with Article 2 of the Basic Law"; and
- From a practical point of view, "at present, there is little likelihood of the sample or record of a criminal offender being stored in a biobank" (the DNA patterns stored in scientific databases are different in structure from the DNA profiles which are prepared in forensic investigations). However, it is possible that in a near future each stored sample is identified by extracting a specific DNA pattern, "in a similar way as this is done with the use of forensic DNA examinations". In such a case, it would then be possible for the same pattern to be extracted from traces at the scene of the crime and to be compared with the patterns of samples in a biobank with the help of an automatic search procedure.

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[21] There are discussions at present as to whether the Swedish Biobank Act should be amended and the possibilities of access for criminal investigations by the police should be extended. Swedish Kommittédirektiv (2008).

Finally, the Opinion suggests that a legal Biobank secrecy should be introduced by a statute, in accordance with EC Data Protection Directives.

7.2.3 Privacy Without Boundaries

The above-considered documents and opinions are extremely interesting for their new and more realistic approach to the issue of access.

In general terms, the need for protection of data that are collected on a confidential basis is reaffirmed, even if it is not clear why some documents do not distinguish between public authorities and private entities and interests (such as insurance companies). I think that when interests at stake have to be balanced, we must weigh them carefully. The state should not be intrusive in private lives (unless it is strictly necessary), but the public need for criminal investigation of serious crimes has an incomparable higher value than the economic interests of a private company.

The proposal of establishing a "biobank secrecy" and the related right to refuse to give information to public and private entities is interesting. But it is surprising how the considered documents and opinions seem to follow the way of unlimited extension of the privacy pattern to each piece of information, even the smallest and the furthest.

Finally, no interest seems to be reserved to familiarity of heritable characteristics and the implications that it has on the interests and the balance between rights and interests.

Familiarity of genetic data and low stringency searches, on the one side, and the interconnection between biobanks, on the other, and envisioned further connections and searches in huge research biobanks—all those aspects, together, weaken national legal guarantees, cross-national borders and seem to make our informational privacy a dream.

7.2.4 Disenchantment on Privacy and Informed Consent

We live in an era marked by many controversial attitudes towards issues like privacy and intrusions in our lives. On the one side, the feeling that we have entered the post-privacy society, where we have lost track of how many entities are tracking us and our behaviours (behavioural tracking), seems to be a matter of common sense, "not to mention what they are doing with our personal information, how they are storing it, whom they might be selling our dossiers to and, yes, how much money they are making from them". [22] As for science and technology, the latest

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[22] Singer (2010).

Eurobarometer survey on the Life Sciences and Biotechnology, based on representative samples from 32 European countries and conducted in February 2010, points to a new era in the relations between science and society.[23] The drafters of the Report stress that among European citizens "the crisis of confidence in technology and regulation that characterised the 1990s is no longer the dominant perspective. In 2010 we see a greater focus on technologies themselves: are they safe? Are they useful?"

One the other side, legal regulations draw a picture of the situation that seems to belong to a completely different world. The Council of Europe adopted on March 2006 a Recommendation "on research on biological materials of human origin" which, dealing with obtaining biological material for research, states that, "information and consent [. . .] should be as specific as possible with regard to any foreseen research uses and the choices available in that respect" (Article 10).[24] They seem to adopt a perspective that implies that each piece of biological material is recognised full (individual) rights and full control for an undetermined period of time.

In such a general scattered landscape, it is not surprising to see what is happening in the field of ethics of biobanking. In a provocative article in *Nature Reviews Genetics,* Lunshof et al. suggest abandoning the illusion of genetic privacy and adopting a more solidaristic approach. They start considering that recent advances in high-throughput genomic technologies are showing concrete results in the form of an increasing number of genome-wide association studies and in the publication of comprehensive individual genome–phenome data sets. As a consequence of this flood of information, the established concepts of research ethics are stretched to their limits, and issues of privacy, confidentiality, and consent for research are being re-examined. Thus, they try to demonstrate "the feasibility of the co-development of scientific innovation and ethics, using the open-consent framework that was implemented in the Personal Genome Project as an example".[25]

The crucial point is "the applicability of confidentiality to large-scale genomic research" as "developments in both medical informatics and bioinformatics show that the guarantee of absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver any longer". Despite the amount of

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[23] Europeans and biotechnology in 2010. Winds of change? A report to the European Commission's Directorate-General for Research by Gaskell et al. (October 2010), available at http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf. Special attention is reserved to Biobanks. However, the results seem to be not so significant given that only 17 % of interviewed people had a minimum idea of what biobanks are (p. 60).

[24] Council of Europe. Committee of Ministers, Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin (Adopted by the Committee of Ministers on 15 March 2006), at https://wcd.coe.int/ViewDoc.jsp?id=977859 (last visited 22 November 2010). Recently, the Italian legislator introduced a new restrictive regulation that forbids *any* use of *any* "human material" without a previous specific authorisation (Art. 170 ter, D.Lgs. n. 131/2010, containing integrations to the Codice della Proprietà Industriale, C.P.I., Gazzetta Ufficiale n. 192, 18 August 2010).

[25] Lunshof et al. (2008).

effort made to improve data safety, some studies have shown that re-identification of individuals is possible through genotype–phenotype inference and through methods such as genealogical information, trail re-identification or so-called dictionary attacks. Thus, the idea of genetic privacy (i.e. an individual's right to protection from non-voluntary disclosure of genetic information) is an illusion.

Consent, which is a fundamental tool of genetic privacy, ends in a *cul-de-sac*, as it is clear by simply considering that even "including the option of re-contacting and obtaining re-consent", which is usually considered a high-level protection of privacy "implies, by definition, maintaining identifiability and traceability of research participants" and, thus, puts participants' privacy at risk.

The authors suggest the following realistic approach:

- The building of any comprehensive genotype–phenotype data collection requires that the individuals from whom these data are derived be fully aware that the data can be and likely will be accessed, shared and linked to other sets of information, and that the full purpose and the extent of further usage cannot be foreseen.
- Individuals should realize that they are potentially identifiable and that their privacy cannot be guaranteed.
- Open consent means that volunteers consent to the unrestricted re-disclosure of data originating from a confidential relationship, namely their health records, and to the unrestricted disclosure of information that emerges from any future research on their genotype–phenotype data set, the information content of which cannot be predicted.
- No promises of anonymity, privacy or confidentiality are made. The leading moral principle is veracity—telling the truth—which should precede autonomy.

At first sight, the approach described above brings a fresh air of realism into a debate which sometimes seemed to be more attentive to a sort of bioethical correctness on autonomy and privacy of individuals than to the understanding of what is really happening in society and how to regulate it. Having said that, I find that the approach taken by Lunshof et al. has the limitation of oscillating from individual rights to duty of solidarity, from the burden of information to researchers' veracity. In doing so, they miss the crucial question: why should any piece of biological materials and information receive the same kind of protection as an individual as a whole? In other words, they overlook legal reasoning and the related need to consider, when talking about rights, up to what extent these rights should be protected and in relation to what kind of interest. This is the point that I will discuss in next paragraphs.

7.3 The Real Interests at Stake

The real interests at stake, when biological materials and genetic information are involved, cannot be overlooked anymore and need to be carefully scrutinised. And thus, what is the real interest of individuals in their own genetic information that is processed in a research biobank? Where does such an interest vanish? What about when information is genetic information about characteristics shared within their biological group? Should each member of the group be entitled to interfere with lives and choices of other group members? And how should the amplitude of the biological group be determined? Should it date back to some common ancestor? If not, where do we draw the boundary line and according to what criteria?

Drawing such a line is essential today if we want to avoid, on the one hand, abuse of personal information and, on the other, paralysis of scientific research because of a privacy overclaim attitude or policy.

7.3.1 Family and Humanity: Is the Human Genome Really Human? What Family?

"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", solemnly states the *Universal Declaration on the Human Genome and Human Rights*, endorsed by the General Assembly of the United Nations on 9 December 1998. Ten years later, the same idea was reaffirmed in the Preamble of the *Additional Protocol to the Oviedo Convention on Genetic Testing,*[26] that explicitly recalls the Universal Declaration and the idea that, "the human genome is shared by all human beings, thereby forming a mutual bond between them while slight variations contribute to the individuality of each human being" and, thus, "the particular bond that exists between members of the same family".

Such solemn statements seem to conceal a tautology: saying that *the human genome is shared by all human beings* does not increase our level of knowledge about what *human being* means and why his genome should be *human*. An example may clarify the point. Although it is well-known that human beings are mostly made of water, this does not imply that such water is *human water* and does not justify the statement *the human water is shared by all human beings*, as it is clear that the water of all (human and not-human) animals and non-animals is the same water.

In a very provocative way John Harris says, "we, humans are already *humanimals*. We know we are descended from apes, but we perhaps need to remind ourselves that this descent is seamless and means that our genetic constitution contains a mixture of the genes of all the creatures, all the other species, that are part of the origin of our transient and transitional species".[27] From a scientific point of view, it has been clarified that the main cause of phenotypic variation, on which natural selection acts, is the mutation of the developmental genes. In other words,

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[26] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes. Strasbourg, 27 November 2008, at http://conventions.coe.int/Treaty/EN/Treaties/html/203.htm. Accessed 24 October 2010.

[27] Harris (2009). See also Saniotis (2007).

nearly the same 20–30,000 genes shared by all multicellular animals express themselves in a different ontological time and space to produce the wonderful animal variability we admire: it is their heterochronic and heterotopic expression that results in the construction of the different animal design and changes. In addition, other genetic forces contribute to the phenotypic variability increasing or decreasing the allelic frequency, e.g. genetic (other than developmental) mutations, genetic drift, modulation of *gene expression*, all of which could produce phenotypic variation, thus contributing to the evolution of new species.[28]

However, even if we would assume the complex issue of humanity to be resolved, another problem remains on the table: which family are we talking about?

When the Universal Declaration on the Human Genome and Human Rights uses the words "the fundamental unity of all members of the human family", it is clearly referring to *family* as a metaphor. Indeed, family does not literally denote humanity as a whole, but nowadays "a fundamental social group in society typically consisting of one or two parents and their children".[29]

The above-quoted Additional Protocol on GT (2008) uses in several parts the words "family" and "family members",[30] although it never explains what exactly family is according to their views, whether a social, biological or legal entity.

Two main attempts have to be reported in this field. A first draft of a new legal concept of family data or shared genetic data was outlined by the European Union Recommendation 1997(5), point *58* of the *Memorandum* to the Recommendation. The drafters approach the issue in the following way: "The collection and processing of genetic data involve the storage of data concerning third parties. These third parties may be constituted by members of the data subject's genetic line or collateral relatives or members of his/her social family. The drafters agreed to accord an intermediate status to members of the data subject's genetic line so as to distinguish them from third parties in the strict sense of the term and to grant them hybrid legal protection".

The statement looks quite original in legal terms. However, unfortunately the European Recommendation defines neither the concepts of *intermediate status* and of *hybrid legal protection*, nor the criteria according to which such a hybrid should be defined (and how to manage conflicts among *third parties* having an *intermediate status* is completely unclear).

A further step is taken by the EU *Working Document on Genetic Data*. With the premise that some well-known characteristics of genetic data such as the fact that genetic information is unique and distinguishes an individual from other individuals, but it may also at the same time reveal information about, and have implications for, that individual's blood relatives (*biological family*), and the fact

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[28] De et al. (2009). I have the pleasure to thank Prof. Carlo Alberto Redi (University of Pavia, I) for helping me in giving an accurate description of this point.

[29] The American Heritage Dictionary of the English Language, Fourth Edition copyright 2000.

[30] In the Preamble, Articles 7, 8 and 18, and the all Chapter VI (articles 13–15) are dedicated to "Tests for the benefit of family members".

that genetic data can characterise a group of persons (e.g. *ethnic communities*), and reveal parentage and family links, and that genetic information is often unknown to the bearer and does not depend on the bearer's individual will since genetic data are non modifiable, they conclude as follows: "a new, legally relevant social group can be said to have come into existence – namely, the biological group, the group of kindred as opposed, technically speaking, to one's family. Indeed, such a group does not include family members such as one's spouse or foster children, whereas it also consists of entities outside the family circle – whether in law or factually – such as gamete donors or the woman who, at the time of childbirth, did not recognise her child and requested that her particulars should not be disclosed – this right being supported in certain legal systems".[31]

Although the situation looks clear enough from a descriptive point of view (even if the use of concepts is less clear and unambiguous[32]), again, no clear response is given to the questions of the amplitude of the biological group and how we should manage the conflicts arising within the biological group.

The precise legal consequences of this argument are not clear yet. At least two scenarios can be imagined. One is that other family members could also be considered as "data subjects" with all the rights that follow from this. Another option is that other family members would have a different kind of right of information, based on the fact that their personal interests may be directly affected.[33] We find ourselves thrown back full circle.

7.3.2 *Where Should We Draw the Boundary Line? Biology*

If we consider humanity as a whole, modern humans originated 100,000–200,000 years ago from pre-modern humans and represent a relatively homogenous species.[34] Two random human individuals on our planet are identical for about 99.9 % of their DNA. Each individual inherits from his or her parents a random set of 23 chromosomes (a chromosome is the single unit in which the nuclear DNA is packed and arranged within the nucleus) present in the gametes. These 23 chromosomes contain half of the genetic programme of the individual (and related genetic variation) and are formed from the complete kit of 46 chromosomes, which contain all the genetic information and are present in all other cells of the organism. Thus, we inherit from each of our parents and we transmit to our children just one of each of the two homologues and related genetic information. The number of

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[31] Article 29 Data Protection Working Party (2004).

[32] Knoppers and Saginur (2005).

[33] Working Group, cit., p. 8.

[34] I am deeply in debt to Prof. Francesco Cucca (University of Sassari, I) who generously and kindly provided me accurate and precious information on the scientific grounds of the issues this paragraph deals with.

46 chromosomes typical of our species is then re-established with the formation of the zygote after the fecundation of one mature maternal gamete (or egg) by one mature paternal gamete (or spermatozoa) and the deriving fusion of the two kits of randomly assembled 23 chromosomes present in these paternal and maternal gametes. Since the two homologues derive from different individuals (the parents), their genetic content is not identical; that is, the genetic instructions contained in the two copies of the same gene are in some points different on the two chromosome homologues.

Stunningly, there are 8.4 million (2^{23}) possible theoretical combinations in the process leading to the generation of the half kit of 23 chromosomes in each parental gamete, which for this reason is always unique. Furthermore, in the randomly selected 23 chromosomes there is also some reshuffling between the chromosomes inherited from the previous parental generation by means of a process named recombination, which determines a further increase of variability and contributes to making each gamete unique. These processes explain why two individuals, even two siblings (with the special exception of monozygotic twins, who result from the fecundation of one egg by one spermatozoa) cannot be genetically identical. Furthermore, it is also evident that as a result of sexual reproduction, variation among contemporary individuals is the cumulative result of past processes before and after the appearance of our species.

It is also evident that, independently of the population of origin the DNA of related individuals is more similar than the DNA of unrelated individuals. For instance, the parents must transmit half of their entire DNA sequence to their children by force of circumstance. This means that parent and child share an extra 50 % of their DNA over and above the baseline value of 99.9 % that all individuals of our species share in any case. Also, two brothers tend to share 50 % of the variable portion of their genome. However, while the genetic relatedness of parent and child is always and exactly defined by a sharing value of 50 %, the relatedness between two brothers is 50 % on average. In fact, the stochastic nature of the chromosomal “lottery” leading to the formation of the half kit of chromosomes in the gametes makes it possible for two brothers to share more or fewer chromosomes, and thus, more or fewer genes, than the average value of 50 %. Child/grandparent pairs or child/uncle pairs tend to share 25 % of the variable portion of their genome. Likewise, first-degree cousins and child/great-grandparent pairs share 12.5 % and, going further in genetic relatedness, second-degree cousins only 3.1 % of the variable portion of their genome. Most importantly, two closely related individuals are not only genetically more similar to each other but they also have a higher probability of a concurrent appearance of genetic variants (including rare ones) than unrelated individuals.

In other words, there is a linear reduction in the co-inheritance of DNA variants with the increasing distance of relationships. Science presents life as a continuum of biological links with several nuances and distances, but no clear boundary and for all aspects.

7.3.3 Where Should We Draw the Boundary Line?

It is now worth turning to general legal regulations of family and verifying whether laws, when they use the word family, refer to the same social and/or biological entity (reserving special attention to its amplitude). Hereinafter, a short list of legal texts is presented.

- The Italian Civil Code (1942) deals with the "Limits of kinship" at Article 77 and states that, "the law does not recognize kinship beyond the *sixth* degree".
- The Italian Guidelines on Genetic Medicine (2004) considers at Article 7 the problem of relatives and information on genetic testing results and states that, "personal data should not be communicated to relatives unless the interested person has given his/her consent [. . .] the relatives to be informed are only those within the *third* degree".[35]
- The Statement on DNA Sampling: control and access (1998), HUGO Ethics Committee, states that, "special considerations should be made for access by *immediate relatives*. Where there is a high risk of having or transmitting a serious disorder and prevention or treatment is available, *immediate relatives* should have access to stored DNA".[36]
- The Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing of Health Purpose (2008), dealing with *Tests on person not able to consent* (Article 13), clarifies that, "the purpose of the test must be to enable family members, with whom the person concerned has a *biological link*, to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation".[37]
- The Universal Declaration on Human Genome and Human Rights, Article 1, solemnly declares that, "the human genome underlies the fundamental unity of *all members of the human family*".[38]

Although incomplete and includes texts of different legal value, this short list makes one point clear: there is no way to reach unanimity within existing legal texts about the boundary of what is called family. There is an astonishing shift from *third* degree, to *sixth* degree, to *immediate relatives*, to (any) *biological link* ending with the metaphor of *all members of the human family*. Even if we can find a reason for such a situation (each legal act and/or document reflects the idea the drafters had in mind in relation with what they aimed to regulate), the temptation to move back to the Francis Galton cosmology is strong: "Neither must we be misled by the word 'individuality', because [. . .] our personalities are not so independent as our self-consciousness leads

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[35] Società Italiana di Genetica Umana (2010).

[36] http://www.hugo-international.org/img/dna_1998.pdf. Accessed 22 November 2010.

[37] http://conventions.coe.int/Treaty/EN/Reports/Html/203.htm. Accessed 22 November 2010.

[38] http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html. Accessed 22 November 2010.

us to believe. We may look upon each individual as something not wholly detached from its parent source. There is decidedly a solidarity as well as a separateness in all human, and probably in all lives whatsoever".[39]

However, as jurists, we should not be seduced by such an undetermined perspective and give up our job saying that because of the biological ties of all humans, there is no reason for distinguishing between individuals and their rights anymore.[40] In a situation where biology is unable to enlighten our path, looking for the degree of genetic distance where the individual interest at stake is still or is no longer worthy of legal protection, the legal approach should elaborate *legal* solutions, taking into account scientific evidence and technological reality (e.g. about the quantitative relevance of information at a certain distance), rather than waiting for prepackaged solutions coming from science.

7.4 Human Individual and Biological Group as Legal Artefacts

It is now worth trying to see whether a thread of legal consistency can be found within such a jumble of biology and law.

7.4.1 From Patriarchy to Bio-Archy?

The *Working Document* seems to suggest that a new general obligation is taking shape within the biological group: the specificity of genetic data makes it necessary to view some aspects of the regulations applying to them in a more than merely individualistic perspective—with particular regard to access to these data by kindred members inside the relevant biological group. Furthermore, issues related to the mechanisms for circulating genetic information within this group arise. These issues concern, in particular, a possible obligation of an individual to disclose his/her genetic data to his/her kindred where such data are relevant in safeguarding their health, and the exercise of the right not to know inside the group. In this context, questions arise as to whether or not genetic data belong exclusively to the single, specific individual from whom they are collected, and whether family members have the right to access such data even in the absence of the individual's consent. To the extent that genetic data has a family dimension, it can be argued that it is "shared" information, with family members having the right to information that may have implications to their own health and future life.[41]

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[39] Galton (1869), p. 373.

[40] See Lunshof et al. (2008).

[41] Working Group, op. cit., p.8.

In short, each of us, while having a unique genetic make-up, belongs to a genetic line which is the common source of all the members of the biological group. This means that our power to exclude the other members in the name of personal ownership fails simply because we do not have any exclusive ownership on that part of inherited characteristics and data. The essential terms of the problem are as follows: if sharing data gives each "share-holder" a right of (non)disposal of data of the other "share-holders", we would no longer have any genetic privacy and the individual's sovereignty would hold out against the applications of genetics. On the other hand, we have an obligation to give a response to the share-holders who need to know more about the genetic data of other share-holders for health reasons. Hence, there is a strong need to balance opposing rights, which have to be carefully evaluated and mutually pondered.

It is important to note that the new obligation stems not from an authoritative relationship, as the relationship citizen-health institutions does. Although deeply involved, family shows in this case its facet made of blood relationship, the facet of biological group, without any (at least at first sight) hierarchical nuance. Or we can say more precisely that there is no stable hierarchy and that the scale of authority is strictly linked and varies according to the importance of the reasons the individual brings in support of his or her claim. It is clear that this hierarchy changes according to the different weights of the interests at stake.

Two different kinds of genealogical tree can be envisaged, the first one is a typical expression of *Patriarchy* (the old family trees of old noble families) and the second one is a family tree like those nowadays used in genetic clinical settings (and represents what can be called *Bio-Archy*). Although they look quite similar (in both ancestors and descendents are represented), the first hierarchy is stable, linear and vertical (from top to bottom), while in the latter the relations are horizontal and hierarchy (or, better, pre-eminence) is not established once and for all.

The above-outlined new obligation (see the passage above quoted from the *Working Document*), adds to the general obligation that everybody has towards public institutions, which are interested in taking advantage of familiarity for the public good, such as safety, crime control or public health reasons. Thus, we probably have to reshape the individual's sovereignty on himself and to imagine him as equipped with a multifaceted and ever-changing set of rights coexisting in his domain, depending on the specific interests that, case by case, he may have and on the nature (public or private) of other subjects possibly involved in the conflict.[42] This is common to all, even economic, rights. The novelty consists in having individual biological source and boundaries implied and the biological and the legal aspects strictly linked, in the sense that the individual domain is eventually enlarged or reduced and, in either case, interrelated with others in ever-changing relations and shapes.

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[42] See above the conclusions of paragraph 4.6.

7.4.2 Chickens, Lands and Genetic Distance (Talking of Rights and Interests)

The relation between legal rights and underlying interests is a conceptual locus in legal theory and, of course, this chapter makes no claim to deal with the huge literature dedicated to the issue.[43]

Nevertheless, the regulation of property/estate rights and the extent to which owner's rights are recognised might be helpful in understanding the real question at stake. It might be likewise helpful in testing the conceptual patterns that we use when dealing with rights recognised and belonging to individuals, their detached parts or their biological materials, the related information and individual's control on information, as well as interference with other group members. Indeed, it is undeniable that the distance from the full person to partially shared information (from non-coding DNA) is very wide and the conceptual shift dramatic.

So let us consider the metaphor of land ownership and the limit to which the owner's interest is recognised by law.

According to both civil law tradition and an ancient doctrine of common law, the landowner's rights extend "from the depths to the heavens" as "to whomever the soil belongs, he owns also to the sky and the depths"[44] [*Cuius est solum, eius est usque ad caelum (ad sidera), et usque ad inferos*]. Such an unlimited claim was seriously hampered by the development of aviation, mining enterprises and other activities that modern technologies made possible in the nineteenth and twentieth centuries.

United States v. Causby is the leading case in the USA in the legal debate of whether property is taken (within the meaning of the Fifth Amendment) by frequent and regular flights of army and navy aircrafts over owner's land at low altitudes. The case was summarised by the Supreme Court as follows: "Respondents [Thomas Lee Causby et ux.] own 2.8 acres near an airport outside of Greensboro, North Carolina. It has on it a dwelling house, and also various outbuildings which were mainly used for raising chickens. The end of the airport's northwest-southeast runway is 2,220 feet from respondents' barn and 2,275 feet from their house. [. . .] Various aircraft of the United States use this: airport-bombers, transports and fighters. [. . .] Since the United States began operations in May 1942, its four-motored heavy bombers, other planes of the heavier type, and its fighter planes have frequently passed over respondents' land buildings in considerable numbers and rather close together. They come close enough at times to appear barely to miss the tops of the trees and at times so close to the tops of the trees as to blow the old leaves off. The noise is startling. And at night the glare from the planes brightly lights up the place. As a result of the noise, respondents had to give up their chicken business. As many as six to ten of their chickens were killed in one day by flying into the

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[43] Macilotti (2008).

[44] Black's Law Dictionary (6th ed. 1990).

walls from fright. The total chickens lost in that manner was about 150. Production also fell off. The result was the destruction of the use of the property as a commercial chicken farm. Respondents are frequently deprived of their sleep and the family has become nervous and frightened. Although there have been no airplane accidents on respondents' property, there have been several accidents near the airport and close to respondents' place".[45]

By flying planes in this airspace, Causby argued, the government had confiscated his property without compensation, thus violating the Takings Clause of the Fifth Amendment.

The Court concluded that the ancient common law doctrine "has no place in the modern world" and Justice Douglas noted that, were the Court to accept the doctrine as valid, "every transcontinental flight would subject the operator to countless trespass suits. Common sense revolts at the idea". However, while the Court rejected the unlimited reach above and below the earth described in the common law doctrine, it also ruled that, "if the landowner is to have full enjoyment of the land, he must have exclusive control of the *immediate reaches* [italics mine] of the enveloping atmosphere". Although not defining any specific limit, the Court stated that flights over the land could be considered a violation of the Takings Clause if they led to "*a direct and immediate interference* [italics mine] with the enjoyment and use of the land". Given the damage caused by the particularly low, frequent flights over his farm, the Court determined that the government had violated Causby's rights, and he was entitled to compensation.[46]

Coming back to biobanking and genetic distance, the question is whether spatial concepts, like *immediate reaches* and *direct and immediate interference*, might work in order to establish the degree of genetic distance where the individual interest at stake is still or no longer worthy of legal protection.

A further step is made possible by the Italian legislation on land property. According to the Italian Civil Code (1942, Article 840), land property extends to the subsoil, and the landowner is permitted to excavate or build without causing damage to neighbours. The most interesting point is in the second part of the article where it is stated that, "the landowner is not entitled to oppose to third party's works extending into the deep subsoil or the space above the land, unless he has a specific interest". It is worth noting that in this legal provision, the interest seems to act as the external boundary of the right. In this light, we may say that the right encompasses normal uses of the land and not uses exceeding the interest of the landowner. Thus, landowner's interest is the limit to the right of land property so that if there is no interest there is no right.

In addition, in order to confirm the crucial importance of the interest (underlying rights) in Italian law, it might be recalled that even in Italian procedural law, whoever files a suit against another party before a judge should have an interest

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[45] United States v. Causby, 328 U.S. 256 (1946).

[46] Among many, see http://www.oyez.org/cases/1940-1949/1945/1945_630.

in it, otherwise, their suit is not admissible and the court has no duty to decide the case (Article 100, Italian Civil Procedural Code).

7.4.3 Weighting Interests in Biobanking

If we move back to informed consent and genetic distance, the question is whether the shift from *persons*, whose protection is at the origin of informed consent doctrine,[47] to the smallest *piece of information,* makes any difference.

Of course, improper uses of my personal information by a third party may produce injury, but all this does not authorise us to skip questions like these: What is personal information? Does any kind of personal information have the same value? May we extend the individualistic pattern to all information related to my person, even the smallest or remote, eventually shared within a wider biological group as far as distant relatives and. . . the Common Ancestor of all humans?

Individual interest is not a general concept having the same extension and weight whatever the issue and context. We have to envisage a way of considering and weighing the interests at stake: individual interests, group interests, public interests, interests of scientific research, and so on.

Such a complex of interests and rights has two sides. The first one is made of full individuals with physical and psychological integrity[48]: they prevail in all cases, with the only limitation of not to harm others. The second one is public interest (assuming that there is a public interest even in scientific research) that prevails in all cases where individuals' rights are not involved. In the middle, there is a vast range of situations where interests at stake face each other in many different kinds of relations. In my opinion, there is no way to escape the duty of evaluating and weighing such interests, if not case-by-case, then at least kind of situation by kind of situation.

Situations should be categorised following clear criteria. Here are some examples:

- Definition of the interest:
    a) According to the kind of activity (research or other)
    b) According to the genetic distance
    c) According to the time that has passed from the collection of a sample and its use and to the kind of use
- Who has the burden of proving his/her interest?

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[47] Nuremberg Code: "... [information on] the effects upon his health or person which may possibly come from his participation in the experiment. [...] The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury".

[48] Art. 3 Charter of Fundamental Rights of the European Union: http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

- Who is entitled to oppose some kinds of use? Generally speaking, we may say that, at a certain genetic distance, the existence of a right (and its underlying interest) has to be demonstrated by whoever is claiming it.
- Public and private interests:
  a) Public interest in scientific research, and thus in biobanking as a powerful tool for genetic research (metaphor: biobanking as railways);
  b) Private interest in specific research, with potentially related economic interests (metaphor: researchers as private trains on public railways).

About the public–private divide, the metaphor of trains and railways may work. There is a clear public interest in railways, but not necessarily in train transportation. Private actors and companies can own trains and not railways.

In conclusion, we may say that rights and/or interests must be weighed taking into account the many facets of the issue and the homogeneity of the terms of comparison.

7.5 Combination of Individuals and Genetic Ties: Law and Science

We may say that our concept of the *individual* has changed in the last few decades. The individual, even if *dividual*, *divisible* or compartmentally constructed from a biological point of view and split in their psychological continuity, seems to have become the sovereign of their own self-defined biological, psychological and social boundaries.[49] Although, at first sight, all that can appear morally controversial or legally questionable, however, on a deeper level all these choices do not appear incongruous, or at least not *per se* incompatible, with the individualistic tradition of modern legal systems. All modern Bills of Rights, openly or implicitly, are based on these individualistic assumptions. Nowadays also, the Preamble of The Charter of Fundamental Rights of the European Union clearly states that the Union "places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice".[50] The only two main limits that the contemporary idea of individual liberty meets were clearly set by John Stuart Mill: not to harm others and not to sell oneself as a slave.

Modern genetics, and the extraordinary disrupting strength of the concept that we belong to a genetic line rather than own our genetic make-up, seem to challenge these ideas. Indeed, modern genetics disclose the 'invisible' part of heredity at the molecular level, "prior to which the information about hereditary traits was limited to what could, in principle, be known to others — such as individual and family

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[49] Santosuosso et al. (2007) and Santosuosso and Bottalico (2009).

[50] See at http://www.europarl.europa.eu/charter/default_en.htm.

health history (even if certain diseases running in the family were kept as a family secret), pedigree information and obvious physical traits".[51] In addition, the biological description of our common source seems to supersede almost all traditional legal concepts and marks the triumph of Galton's prophecy on overvaluation of "individuality".

At this point, should we say that the sovereignty of the individual and Mill's dowry of liberty yield to the overwhelming power of genetic ties? In my opinion, an attitude like this would be conceptually wrong because it does not correctly discriminate between biology and law. In order to clarify this assertion, two points are crucial: Kelsen's concept of the juridical physical person as a creation of the law and Mill's idea of combination of individuals as one of the expressions of individual liberty.

According to Hans Kelsen, "to define the physical (natural) person as a human being is incorrect, because man and person are not only two different concepts but also the results of two entirely different kinds of consideration. Man is a concept of biology and physiology, in short, of the natural sciences. Person is a concept of jurisprudence, of the analysis of legal norms".[52]

The answer to the further facet of the question on what constitutes the kind of unity we call physical (natural) person is as follows: "the human being is not the physical (natural) person but, so to speak, only "the compass" of a physical (natural) person. The relation between a so-called physical (natural) person and the human being with whom the former is often erroneously identified consists in the fact that those duties and rights which are comprised in the concept of the person all refer to the behaviour of that human being".

Thus, according to Kelsen, "since the concept of the so-called physical (natural) 'person' is only a juristic construction and, as such, totally different from the concept of 'man', the so-called 'physical' (natural) person is, indeed, a 'juristic' person. If the so-called physical (natural) person is a juristic person, there can be no essential difference between the physical (natural) person and what is usually exclusively considered as a 'juristic' person".

In brief, the main points of Kelsen's concept of person can be summarised as follows: (a) the human being, as *biological entity*, is a different entity than the physical person in legal terms; (b) the human being is the basis of the physical person in legal terms as a *symbolic and linguistic unity*; (c) the *biological* human being is only the *enclosing line* (Kelsen uses the word compass, in double quotes) of a physical person in legal terms; (d) the human being exists in the law only for the limited extent to which rights and duties refer to him; and (e) the physical person in legal terms and the juristic person (i.e. corporation) are both legal creations having in common the character of artificiality.

On the other side, John Stuart Mill outlines very clearly the different aspects of individual liberty: "there is a sphere of action in which society, as distinguished

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[51] Lunshof et al. (2008).

[52] Kelsen (1945), Part One, Chapter IX, A-B, pp. 93–95.

from the individual, has, if any, only an indirect interest; comprehending all that portion of a person's life and conduct which affects only himself, or, if it also affects others, only with their free, voluntary, and undeceived consent and participation. [. . .] This, then, is the appropriate region of human liberty. It comprises, first, the inward domain of consciousness; demanding liberty of conscience [. . .] Secondly, the principle requires liberty of tastes and pursuits; of framing the plan of our life to suit our own character; of doing as we like, subject to such consequences as may follow; without impediment from our fellow-creatures, so long as what we do does not harm them even though they should think our conduct foolish, perverse, or wrong. Thirdly, from this liberty of each individual, follows the liberty, within the same limits, of combination among individuals; freedom to unite, for any purpose not involving harm to others: the persons combining being supposed to be of full age, and not forced or deceived".[53]

At this point, the question is as follows: can the ideas of the physical person as a legal artefact and the combination of free individuals be of some help in one of the main critical points of biobanking, i.e. that of the extension of privacy beyond the individuals and genetic distance?

Kelsen's theory is one of the pillars of modern legal thinking and, even if not unquestioned in its general terms, is surely very productive and convincing in the issues where the law faces scientific applications. More complex is the reference to Mill's combination of individuals. Of course, when writing about such combination, Mill was thinking about everything but genetic ties and biological group. However, if we consider the new fragments of the law on shared genetic characteristics (e.g. *The Working Document*) and the prior place that autonomous individual choices still have and the importance (in case of litigation within the biological group members) of the basic rule *audiatur et altera pars* and the need to recognise the prevalence of a right or another according to the underlying interest, if we consider all these, the shape of the so-called biological group no longer looks like a *biological* entity thrown into the *legal* field and challenging its internal consistency. It rather looks like a *legal* entity (not dissimilarly than the physical person for the law), whose shape is the result of all individual choices that the members make, widening or narrowing the group compass. We may say that the biological group, if seen in its legal relevance, is a free combination of persons and, thus, an artificial legal entity.

One could object that in this field nothing is free, because of genetic ties and a strong common biological source. I do not think so. The position every member of the biological group takes may be considered as a party's will in a free contract. Of course, genetic ties exist. However, they are only the occasion for a stipulation within free individuals. In some sense, the decisions of persons (who bear a reasonable interest) "create" the genetic tie or, at least, make it relevant.[54]

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[53] Mill (1859), Chapter I.

[54] Of course, this does not solve all the problems, because the condition of full age, and not forced or deceived person is not always possible and we have to decide how to deal with incompetent people. However, this is a not new problem and it is well known in all patient autonomy literature.

In more general terms, the conclusion could be that the human individual and the biological group compass are legal artefacts, whose definitions are under the responsibility of individuals and lawmakers, who should be aware of scientific findings and background.

7.6 Should Privacy Be Abolished in Genetics and Biobanking?

The answer to the main issue of this work (whether privacy should be abolished in genetics and biobanking) is 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.

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