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“ADIÓS SUI GENERIS”
A STUDY OF THE LEGAL FEASIBILITY OF THE *SUI*
***GENERIS* RIGHT IN THE CONTEXT OF RESEARCH**
BIOBANKS

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“ADIÓS SUI GÉNERIS”
A STUDY OF THE LEGAL FEASIBILITY OF THE *SUI*
***GENERIS* RIGHT IN THE CONTEXT OF RESEARCH**
BIOBANKS

ABSTRACT

The European protection of databases has been criticized for having a negative impact on the scientific development and the process of discovery. In the paper it is checked whether one of the most important research infrastructures, such as biobanks, could be entitled with the *sui generis* right as shaped within the current European legal system.

KEYWORDS

Biobank – Genetic database – Intellectual Property - Copyright - *Sui generis* right – Data sharing

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“Adiós Sui Géneris”. A study of the legal feasibility of the *sui generis* right in the context of research biobanks¹

SUMMARY: 1. Introduction – 2. The legal protection of the database in Europe - 3 . Biobanks and the sui generis right: a possible relationship? - 4. Conclusion

1. Introduction

Over the last years, biomedical research has experienced terrific development, thanks to the advancements of the information and communication technology (ICT), the creation of research infrastructures, such as biobanks, and the increasing investments, mainly coming from the public sector. At the core of this type of research, there is the bioinformation: the growth of the biomedical sector dramatically depends both on the availability and reliability of data and biomaterials, and on the possibility of enhancing the data sharing.

In this scenario, the role of technology has been twofold: it has profoundly changed both the traditional research methods and the social dynamics towards data sharing. On the one hand, new sophisticated instrumentation devices have allowed a richer and more detailed molecular analysis of biological and DNA samples, producing a huge amount of data and information almost unimaginable twenty years ago. On the other hand, data, information, materials and scientific findings are captured, summarized, and, above all, shared in a more efficient and quick way due to the ICT, which fosters the information retrieval, the comparison between communities of practices, the validation of the results, etc. That is why the container of this information, namely a database, is growing in importance for the scientific community and it is changing the social norms governing it. As Paul David pointed out: «for open science research communities, databases are dynamic tools, not merely static sources to be passively consulted; they are formed and kept effective through an interactive process of

¹ The idea for this paper grew out of a conversation that I had with Thomas Margoni during a research period at the IViR (University of Amsterdam). I wish to thank him for his valuable suggestions and encouragement in deepening this issue.

examination, error-correction, updating, and incremental elaboration that engages the critical expertise of many individuals in the communities of researchers who co-operate in developing, certifying and maintaining these research instruments. Thus, in many contexts the value of the information to users is enhanced by the very fact that its use has been, and will continue to be shared with other researchers»².

All the aforementioned factors are of paramount importance in a sector, such as the biomedical one, which is characterized by the interdisciplinarity and the interaction among professionals with different scientific backgrounds, often located miles away one from each other.

Although in the last few years a significant improvement in the quantity and quality of the information's production as well as a strengthening of the tools to share it have occurred, there are still some problems that hinder the exploitation of this tremendous potential. The obstacles are mainly of technological, socio-economical and legal nature.

Firstly, from the technological point of view, the data sharing may be hampered by the lack of common standards or interoperability among systems, and by the problems of web-semantic and web-ontology—that are currently at the center of the bioinformatics' debate³.

Secondly, with all due respect to Merton, a researcher is not inclined to voluntarily share his or her collection of data and preliminary results before they have been published or patented. An archive of data is a basic resource on which the researcher's academic prestige, his or her career progression, the chance to win grants, or the ability to support his or her research group can depend. For all these reasons, it is easy to understand why these resources are a little “treasure” for the one who sets them up and why they are not so freely shared⁴.

Lastly, the legal regime is also making more difficult to promote the data sharing and the spread of knowledge. We are facing a phenomenon which has been labeled by James Boyle as «the

² DAVID, Paul Alan, A Tragedy of the Public Knowledge «commons»: Global Science, Intellectual Property and the Digital Technology Boomerang”, SIEPR Discussion Paper No. 00-02, 2001, available at: <http://www.stanford.edu/group/siepr/cgi-bin/siepr/?q=system/files/shared/pubs/papers/pdf/00-02.pdf>

³ KANGUEANE, Pandjassarame, Bioinformation Discovery: Data to Knowledge in Biology, Springer-Verlag, New York, USA, 2009.

⁴ GITTER, Donna, “The Challenges of Achieving Open Source Sharing of Biobank Data”, Comparative Issues in the Governance of Research Biobanks, PASCUZZI, Giovanni/ IZZO, Umberto/ MACIOTTI, Matteo (Eds.), Springer, Germany, 2013, pp. 165 ff.

second enclosure movement»⁵, where intellectual property rights (IPRs) have expanded so fast and beyond control, thus undermining the boundaries of the public domain⁶: the case of the recognition of audiovisual rights for sport events, the legal protection of domain name, the ban of mash up, the grant of a patent for gesture movies (sic!)⁷ are a manifestation of this trend. Such an “enclosure” is also taking place in the field of biomedical research. The human genome offers two valid examples in this sense: (a) an isolated gene can be patented⁸, and (b) an assemblage of facts, such as a collection of DNA samples and related data, can be covered by copyright or *sui generis* right according to the European law.

The expansion of the notion of patent-eligible subject matter is critical in the biomedical field, but the swelling of copyright and *sui generis* right risks to jeopardize the free flow of information in a more silent and subtle way. This is particular evident if we consider biobanks. They are powerful tools and organizational structures, which are crucial for the biomedical research, as they provide essential information: they systematically collect and store human biological samples in a professional way and according to high standards of quality and safety⁹. These samples are a source of information (genetic, health, biochemical, molecular information) and they are generally linked to data coming from other sources,

⁵ BOYLE, James, “The second enclosure movement and the construction of the public domain”, Law and contemporary problems, Duke Law School, Núm. 1-2, Vol. 66, Durham, USA, 2003, pp. 33 y ss. See also ID., The public domain: enclosing the commons of the mind, Yale University Press, New Haven, USA, 2008.

⁶ RESTA, Giorgio, Diritti esclusivi e nuovi beni immateriali, Wolters Kluwer Italia, Milano, Italy, 2010.

⁷ ORDING, Bas/ JOBS, Stephen, “Gesture Movies”, available at <http://www.google.it/patents?id=ySjIAAAAEBAJ>.

⁸ With regards to the the gene patents, it is relevant to mention the recent opinion of the US Supreme Court on the “Myriad saga”. The issue at stake was precisely about the patentability of the sequence of two genes, BRCA-1 and BRCA-2, which are two human caretaker genes linked to breast and ovarian cancer. The Court unanimously ruled that DNA as such is a product of nature and, as a consequence, it is not patent eligible; instead, the cDNA (i.e. the synthesized DNA deprived of the segment that do not code for proteins) is a patentable subject's matter. This decision cannot be considered as an overruling of the precedent *Diamond v. Chakrabarty* (in fact, the Court confirmed the precedent, see p. 11), but it undoubtedly reduces the area of the gene patentability. See *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U. S. ____ (2013), slip opinion available at: http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf

⁹ For a more thorough definition, see ORFAO DE MATOS, Alberto, “Biobancos”, Enciclopedia de bioderecho y bioética, ROMEO CASABONA, Carlos María (Ed.), Comares-Roche Institute, España, Vol. 1, 2011; ROMEO MALANDA, Sergio, “Biobancos”, Enciclopedia de bioderecho y bioética, ROMEO CASABONA, Carlos María (Ed.), Comares-Roche Institute, España, Vol. 1, 2011.

such as the clinical history of an individual person. So, basically, biobanks have, or can be considered as, databases and, for this reason, are eligible for copyright or *sui generis* protection.

Nevertheless, looking at the uniqueness of human genome and the scarcity of tissues, such a protection can produce a typical monopolistic effect: due to the restrictions to access, use and share of basic and pre-competitive information, the copyright or *sui generis* protection can create negative externalities for the whole society and the progress of future research. In fact, *sui generis* right has been criticized by legal scholars for its anticompetitive nature and its inefficiencies¹⁰: it represents a European anomaly that should be repealed for economical and social reasons¹¹. The value of that opinion can be observed from a *de iure condendo* perspective; however, in this paper a different aspect is stressed.

Many scholars argue too easily that a biobank can get the *sui generis* right protection, but they do not examine deeply the concrete feasibility of such a statement¹². According to me, the issue needs a further reflection that is able to offer a different interpretation, if properly and in-depth discussed.

¹⁰ For a panoramic of the vast literature, see TROSOW, Samuel, “Sui Generis Database Legislation: A Critical Analysis”, Yale Journal of Law & Technology, Yale Law School, Vol. 7, New Heaven, USA, 2005, pp. 534 ff.

¹¹ Ibidem.

¹² Ex multis, KAYE, Jane/WENDEL, Lotta/HELGASON, Hordur Helgi/SILD, Tarmo/NOMPER, Ants, “Population genetic databases: a comparative analysis of the law in Iceland, Sweden, Estonia and the UK”, Trames, Estonian Academy, Num. 1-2, Tallin, Estonia, 2004, pp. 15 ff.; DG, E. C. E., “Report on the Implementation of the European Charter for Small Enterprises: Communication from the Commission to the Council and the European Parliament”, Office for Official Publications of the European Communities, Bruxelles, Belgium, 2005; GIBBONS, Susan/ HELGASON, Hordur Helgi/ KAYE, Jane/NOMPER, Ants, “Lessons from European Population Genetic Databases: Comparing the Law in Estonia, Iceland, Sweden and the United Kingdom”, European Journal of Health Law, Martinus Nijhoff, Vol. 12, Leiden, The Netherlands, 2005, pp. 103 ff.; LAURENT, Philippe/VILCHES ARMESTO, Laura, “The intellectual property of medical data: copyrights to patients’ records and database rights to biobanks?”, La protection des données médicales: les défis du XXIe siècle, HERVEG Jean (Ed.), Anthemis, Belgium, 2008, pp. 153 ff.; DE ROBBIO, Antonella/CORRADI, Antonella, “Biobanche in bilico tra proprietà privata e beni comuni: brevetti o open data sharing?”, JLIIS.it, University of Florence, Num. 2, Vol. 1, Firenze, Italy, pp. 305 ff.; GOEBEL, Jürgen/ PICKARDT, Thomas et al., “Legal and ethical consequences of international biobanking from a national perspective: the German BMB-EU Coop project”, European Journal of Human Genetics, Nature Publishing Group, Num. 5, Vol. 18, New York, USA, 2010, pp. 522 ff.; BYGRAVE, Lee, “The Data Difficulty in Database Protection”, University of Oslo Faculty of Law Research Paper, n.º 2012-18, 2012, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2088018; DOVE, Edward/ JOLY, Yann, “The Contested Futures of Biobanks and Intellectual Property”, Teorder, McGill University, Num. 11, Montreal, Canada, 2012, pp. 132 ff.

On the basis of this premise, I aim at demonstrating whether, in a *de iure condito* perspective, the *sui generis* right can be concretely applied to the context of research biobanks. In order to verify this, I will firstly analyze the legal framework of database protection, as outlined by the European Union law and case law. Secondly, through the application of the concepts as resulting from the European context. I am going to check whether the research biobanks can claim the *sui generis* right to be referred to their collections of biological materials and information.

2. The legal protection of the database in Europe.

Directive 96/9/EC has introduced the legal framework for databases, articulating the protection according to a double track regime¹³. Besides the protection offered by copyright law (Chap. II), the Directive provides a *sui generis* right to the maker of the database (Chap. III)¹⁴.

Copyright protects databases, which «by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation» (Article 3). It should be specified that the protection is not extended to database content or the existing rights over it. So, copyright covers the expression of the database, and the originality of its systematic organization. The author's intellectual contribution lies in the level of the handiness of the users' access and

¹³ Directive 96/9/EC of the European Parliament and of the Council on the legal protection of databases, in O.J.U.C., series L, 27th March 1996, n. 77, p. 20. The directive has been transposed by the Legislative Decree 6th May 1999, n. 169, amending the Italian Copyright Law (Statute Law n. 633/1941). The directive defines the database as «a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means» (Article 1). This protection cannot be referred to «computer programs used in the making or operation of databases accessible by electronic means». The provision sprang from the need to avoid normative conflicts, in particular, with the directive 91/250/EC on the legal protection of computer programs. RONCONI, Franco, «Trapianto e rielaborazione del modello normativo statunitense: il diritto d'autore di fronte alla sfida digitale», I diritti sulle opere digitali, PASCUZZI, Giovanni/ CASO, Roberto, CEDAM, Italy, 2002, p. 193.

¹⁴ For a deeper analysis, see HUGENHOLTZ, Bernt, «Implementing the European Database Directive», International Intellectual Property Law & Policy, Juris Publishing, Vol. 4, New York, USA, 2000, pp. 70 ff.; DAVISON, Mark, The Legal Protection of Databases, Cambridge University Press, UK, 2003; BEUNEN, Annemarie, Protection for Databases: The European Database Directive and Its Effects in the Netherlands, France and the United Kingdom, Wolf Legal Publishers, Oisterwijk, The Netherlands, 2007; DERCLAYE, Estelle, The Legal Protection of Databases: A Comparative Analysis, Edward Elgar Publishing, Cheltenham-Camberley, UK, 2008.

in the original disposition of the contents. This goal can be reached through the creation of types of data, thesauri, indexing and cross-reference systems, where the author's creativity plays a key role¹⁵. Therefore, if the structure is original, and data are organized in a creative manner - for example, not simply alphabetically or chronologically ordered - the databases's author is entitled to the moral and economical rights¹⁶. The copyright protection of databases, as usually, lasts 70 years after the author's death.

As one can easily imagine, achieving the standard of originality in the database structure is quite difficult. So, in order to counterbalance this "thin protection" and to offer a more efficient remedy against the ease of the copy permitted by digitization, the Directive at stake has introduced a further right – the so called "*sui generis*" – which is granted to the person who takes the initiative and the risk of investing (i.e., the maker of the database).

Such a right is a peculiarity of the EU system and it has been introduced with the intent to protect those databases that, notwithstanding their originality, have been the fruit of the investment of considerable human, technical and financial resources and that can be otherwise frustrated by unauthorized access to and copy of their elements (Recital 7)¹⁷.

The right which is recognized by the Directive to the maker of a database is of utmost importance. The maker can prevent the extraction and/or the re-utilization of the whole or of a substantial part – which is qualitatively and/or quantitatively evaluated - of the contents of that database (Article 7.1). So, the maker of the database can inhibit the permanent or temporary transfer of all or a substantial part of the contents of a database to another subject by any means or in any form, such as the on-screen display of the contents (Recital 44). He/She may also transfer, assign or grant his/her *sui generis* right under a contractual license (Article 7.3).

This right has a hybrid nature: (a) it is unknown in the conceptual baggage of copyright and presents profiles of overlapping with unfair competition; (b) it does not provide a moral right; (c) it is also

¹⁵ IMPERIALI, Riccardo, IMPERIALI, Rosario, "La tutela giuridica delle banche dati", *Diritto comunitario e degli scambi internazionali*, Editoriale Scientifica, Num. 2, Vol. 35, Naples, Italy, 1996, pp. 377.

¹⁶ About the originality's criteria in the U.S.A. see the leading case *Feist Publications Inc. v. Rural Telephone Service Co.*, 499 U.S. 340 (1991). In that case, it was ruled out that facts (e.g., an alphabetic list of a telephone directory) cannot be subject to copyright law.

¹⁷ There are similar forms of protection in the English and Irish legal system (the so-called doctrine of the "sweat of the brow") and in Scandinavian countries (the catalogue rule). See LUBENS, Rebecca, "Survey of Developments in European Database Protection", *Berkeley Technology Law Journal*, UC Berkeley, Vol. 18, Berkeley, USA, 2003, pp. 447 ff.

granted to companies and firms; and (d) it does not require a minimum standard of creativity¹⁸. The only requirements are: (a) the investment; (b) the substantiality of the investment which is evaluated in qualitative and/or quantitative terms; and (c) the use of the investment in the phases of obtaining, verification or presentation of the contents¹⁹.

Unfortunately, the Directive does not deepen the description of the content of such requirements; therefore this gap has been essentially filled both by legal scholars and the case law of the European Court of Justice (ECJ).

Hence, the investment has been broadly interpreted, including various sorts of costs such as, for example, the financial resources, but also the expenditure of time, effort and energy²⁰.

Regarding the interpretation of the quantitative and qualitative aspect, in 2004 the European Court of Justice (ECJ) has clarified that: «the quantitative assessment refers to quantifiable resources and the qualitative assessment to efforts which cannot be quantified, such as intellectual effort or energy, according to the 7th, 39th and 40th recitals of the preamble to the directive»²¹. So, basically, the time and the money invested in the database integrate the quantitative component, while the effort and energy refer to the qualitative component of the substantial investment²². The two elements (quantity/quality) have to be considered as an alternative, but what is important to stress is that both the terms are related only to the type of the investment and not to the quantity or quality of the data or elements that are assembled in the database²³.

Lastly, the ECJ has addressed a critical issue regarding the

¹⁸ According to the European directive, the beneficiaries of protection under the *sui generis* right can be also companies and firms, as long as «formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community; however, where such a company or firm has only its registered office in the territory of the Community, its operations must be genuinely linked on an ongoing basis with the economy of a Member State» (Article 11.2).

¹⁹ Article 7(1).

²⁰ DERCLAYE, Estelle, *The Legal Protection of Databases: A Comparative Analysis*, Edward Elgar Publishing, UK, 2008, pp.73-75. See also, See European Court of Justice 9 November 2004, cases C-46/02 (*Fixtures Marketing Ltd v. Oy Veikkaus Ab*), ECR 2004, p. I-10365; C-338/02 (*Fixtures Marketing Ltd v. Svenska Spel AB*), ECR 2004, p. I-10497; and C-444/02 (*Fixtures Marketing Ltd v. Organismoa Prognostikon Agnon Podosfairou AE (OPAP)*), ECR 2004, p. I-10549; C-203/02 (*The British Horseracing Board Ltd and Others/William Hill Organization Ltd*).

²¹ European Court of Justice 9 November 2004, cases C-46/02 (*Fixtures Marketing Ltd v. Oy Veikkaus Ab*), ECR 2004, p. I-10365.

²² DERCLAYE, Estelle, *The Legal Protection of Databases: A Comparative Analysis*, Edward Elgar Publishing, UK, 2008, p. 91.

²³ *Ibidem*.

function and the types of costs that may count towards the investment. Echoing an argument of the so called “spin-off theory”²⁴, the ECJ made a precise distinction between the creation and the obtaining of data, stating that: «the expression ‘investment in ... the obtaining ... of the contents’ of a database must [...] be understood to refer to the resources used to seek out existing independent materials and collect them in the database, and not to the resources used for the creation as such of independent materials. The purpose of the protection by the *sui generis* right provided for by the directive is to promote the establishment of storage and processing systems for existing information and not the creation of materials capable of being collected subsequently in a database»²⁵.

Some authors justified this conclusion as an attempt to cope with a weak point of the Directive, such as the absence of a compulsory license regime in the case of sole-source database²⁶. However, despite this apparent clarification, the issue of how to identify a clear boundary between generating and gathering data can be difficult in practice. The question at stake is the following one: is the researcher who extracts a genetic sequence from a tissue creating or obtaining the information?²⁷. This «quasi-insoluble question»²⁸,

²⁴ The spin-off theory emerged in 1997 in the Dutch case law and it quickly spread over other jurisdictions with different fortune. In a nutshell, according to this doctrine, only those investments related to the production of the database and not to the creation of the data can be protected. In other words, if the database is a mere spin-off of the primary activity, i.e., a secondary result which is obtained in the context of a broader project, it cannot be eligible for the *sui generis* protection. This conclusion has been explained in the following terms: «the database right is not a right of intellectual property rooted in notions of natural justice, but a right based on utilitarian (instrumentalist) reasoning. In the light of this incentive rationale there would appear to be no reason to grant protection to data compilations that are generated quasi ‘automatically’ as by-products of other activities». DAVISON, Mark /HUGENHOLTZ, Bernt, “Football fixtures, horse races and spin-offs: the ECJ domesticates the database right”, European Intellectual Property Review, Sweet and Maxwell, Num. 3 Vol. 27, London, UK, 2005, pp. 113 ff.; also available at: http://www.ivir.nl/publications/hughholtz/EIPR_2005_3_databaseright.pdf

²⁵ See European Court of Justice 9 November 2004 cases C-46/02; C-203/02; C-338/02; C-444/02. For a comment, DERCLAYE, Estelle, “The Court of Justice interprets the database *sui generis* right for the first time”, European Law Review, Sweet and Maxwell, Num. 3, Vol. 30, London, UK, 2005, pp. 410 ff.

²⁶ DERCLAYE, Estelle, “Databases *sui generis* right: should we adopt the spin off theory”, European Intellectual Property Review, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, pp. 402 ff.; DAVISON, Mark /HUGENHOLTZ, Bernt, “Football fixtures, horse races and spin-offs: the ECJ domesticates the database right”, European Intellectual Property Review, Sweet and Maxwell, Num. 3 Vol. 27, London, UK, 2005, pp. 113 ff.

²⁷ DAVISON, Mark /HUGENHOLTZ, Bernt, “Football fixtures, horse races and spin-offs: the ECJ domesticates the database right”, European Intellectual Property Review, Sweet and Maxwell, Num. 3 Vol. 27, London, UK, 2005, pp. 113 ff.

which shows a systematic or even philosophical nature, is likely to lead us astray. The point is crucial and it will be better addressed in more detail in the next paragraph.

At this level, it is necessary to delineate a final point: even if the database is a mere spin-off, this does not *a priori* exclude the validity of the *sui generis* protection. As the ECJ affirmed, the maker of the database can still claim for the *sui generis* right if he/she proves to have made an additional (substantial) investment in the obtaining, verification or presentation of the contents, and such investment is different of that *occurring* for the creation of data²⁹.

Just to conclude with the main features of the *sui generis* provisions, it should be said that the lawful users of a database, in the hypothesis in which it is made available to the public, must not perform acts which conflict with normal exploitation of the database. Moreover, they can neither unreasonably prejudice the legitimate interests of the maker of the database, nor cause prejudice to the holder of a copyright or related right in respect of the works or subject matter which is contained in the database (Articles 8.2 – 8.3). They can extract or re-use insubstantial parts of the contents of the database (Article 8.1), but not in a repeated and systematic way (Article 7.5).

Finally, about the duration, the *sui generis* right shall expire 15 years from the 1st January following the date of completion or, in the case of a database which is made available to the public, the term of protection runs from the 1st January of the year following the date when the database was first made available to the public (Article 10).

The European dual systems of database protection and, chiefly, the vagueness of the *sui generis* right and its scope have raised several concerns from a legal point of view³⁰.

²⁸ DERCLAYE, Estelle, “Databases sui generis right: should we adopt the spin off theory”, European Intellectual Property Review, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, pp. 402 ff.

²⁹ European Court of Justice 9 November 2004, C-203/02 (The British Horseracing Board Ltd and Others/William Hill Organization Ltd).

³⁰ See: DG Internal Market and Services Working Paper, *First evaluation of Directive 96/9/EC on the legal protection of databases*, available at http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf. It is a right “under supervision”: indeed, every three years the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on the application of the directive, in which, on the basis of specific information supplied by the Member States, it shall examine in particular the application of the *sui generis* right, and it shall verify especially whether the application of this right has led to abuse of a dominant position or other interference with free competition. If such abuse or interference occurs, this would justify the adoption of appropriate measures, included the establishment of non-voluntary licensing arrangements. Where it is

In particular, the *sui generis* right has been at the core of the debate for its potential negative consequences, such as the perils of excessive monopoly, the increased transactions costs, and the interference with data aggregation³¹.

The educational and research exemption (Article 6) proves not to be a sufficient antidote against the danger of the blocking of information flow, and, as a matter of fact, the legitimate uses for educational or scientific purposes are not even considered by some national implementations of the Directive, such as in the case of Italy (see Article 102-bis, Statute Law n. 633/41).

In addition, the 15-year exclusive right recognized to the maker of the database looks like the monopoly granted to the patent, but it is even more pervasive: through the mechanism of substantial changes (Article 10.3), the power to inhibit the extraction or re-use can be extended without real time-limits³². This possibility is made concrete by the use of technological protection measures (Article 102-quarter, Statute Law n. 633/41).

This proprietary regime towards database is able to pose serious obstacles to full and open access to data for scientific purposes. Both academic and research communities perceived the *sui generis* right as «one of the least balanced and most potentially anti-competitive intellectual property rights ever created»³³.

The viability of the *sui generis* right in the field of biobanks - which are structures with the institutional goal to promote scientific research, balancing the freedom of science/ist with the interest of participants and the public - has therefore raised a number of concerns. However, in order to allay these fears, it is necessary to verify in practice whether all the criteria for the occurrence of the *sui generis* right are fulfilled in the case of research biobanks.

necessary, the Commission shall submit proposals for adjustment of this Directive in line with the developments in the area of databases (art. 16).

³¹ TROSOW, Samuel, "Sui Generis Database Legislation: A Critical Analysis", Yale Journal of Law & Technology, Yale Law School, Vol. 7, New Haven, USA, 2005, pp. 534 y ss. See also, ICSU, "Report of the CSPR Assessment Panel on Scientific Data and Information", 2004, available at: <http://www.science-softcon.de/cspr.pdf>.

³² IMPERIALI, Riccardo, IMPERIALI, Rosario, "La tutela giuridica delle banche dati", Diritto comunitario e degli scambi internazionali, Editoriale Scientifica, Num. 2, Vol. 35, Naples, Italy, 1996, pp. 377.

³³ REICHMAN, Jerome/SAMUELSON, Pamela, "Intellectual Property Rights in Data?", Vanderbilt Law Review, Vanderbilt University, Vol. 50, Nashville, USA, 1997, pp. 52 ff.

3. Biobanks and the *sui generis* right: a possible relationship?

Biobanks are organizational structures which are aimed at the collection of biological materials for research purposes. They are formed by a biorepository, where the samples are cryoconserved, and an electronic database, within which the “metadata” relating to the sample (e.g., tissue type, date of sampling, assigned barcode) are indexed, as well as the data which are derived from the analysis performed on the same biomaterial. Such data can therefore consist of measurements, observations, images, genetic analysis, and phenotypic or genotypic information. In the light of their structure, biobanks can therefore be considered as a database within the definition of Article 1 of the Directive 96/9/EC³⁴.

Considering the type of materials and the purpose for which they are collected, it is difficult to figure out a minimum standard of creativity in the organization of the biobank’s database. The samples are stored according to the type of pathology, tissue or molecule analyzed and they are identified by an alphanumeric code. The data contained in the electronic database are sorted according to trivial criteria as well. As a result, such databases tend not to meet the requirements to be protected under copyright.

However, creativity is not a precondition for the *sui generis* right. For this reason, this type of right could be referred to the case of research biobank’s database. Therefore, it is necessary to check whether the substantial investment is in this case aimed at the obtainment, verification or presentation of the database’s content. As mentioned, the elements of a biobank’s database can lie in tissues, biological samples, cells, genetic data, health information, and the maker of the biobank indubitably invests a substantial amount of resources in order to “have” them. Indeed, it is necessary to recruit patients or volunteers to obtain the samples; in some cases, the volunteers are paid or compensated; sometimes they have to be recontacted; the sample extraction requires different types of costs (staff, instruments, etc.), and its following essay has to be performed through highly specialized personnel and equipment; and so forth. Just to give an idea of the amount of the costs, a small-medium biobank collecting less than 600 cases of cancerous tissues requires

³⁴ In fact, the Directive does not protect only the electronic database. According to art. 1: «This Directive concerns the legal protection of databases in any form. For the purposes of this Directive, 'database' shall mean a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means».

an investment of around 150.000 Euro per year only with reference to the hiring of the personnel³⁵.

The critical point is to understand whether such costs are direct to the obtaining of the data rather than to their creation. The problem arises because of the peculiar nature of the elements collected in a biobank's database. In fact, on the one hand, biological samples and genomic data exist in nature before being extracted or processed by a researcher. The human effort does not invent them from scratch. On the other hand, such elements pre-exist in nature, but in a different way: before the ablation, the biological sample is part of the organism, it contributes to its functions, and is not possible to identify it as a separate component immersed in isopentane³⁶; before the processing, genetic data is a flux of information in the form of an encoding biological message and not a string of bits. The data are a representation of a natural phenomenon and not the phenomenon itself³⁷. They naturally occur in nature, but only the human effort is able to translate them in an intelligible form, giving them a new shape, a new ontological existence. Therefore, according to the stricter interpretation of the term "obtaining" as pointed out by the 2004 decisions of ECJ, biological samples and data collected in the biobank not are simply gathered, but actually created³⁸.

³⁵ The data comes from the example of the Trentino biobank (www.tissuebank.it). See also BARBARESCHI, Mattia et al., "Biobanks: instrumentation, personnel and cost analysis", *Pathologica*, Pacini Editore, Vol. 100, Ospedaletto (Pisa), Italy, pp. 144 ff.

³⁶ Isopentane or liquid nitrogen are the most common methods for the cryoconservation of samples in a biobank.

³⁷ DAVISON, Mark/HUGENHOLTZ, Bernt, "Football fixtures, horse races and spin-offs: the ECJ domesticates the database right", *European Intellectual Property Review*, Sweet and Maxwell, Num. 3 Vol. 27, London, UK, 2005, pp. 113 ff.

³⁸ *Ibidem*. Davison and Hugenholtz affirmed the same principles with reference to scientific data in general. According to the authors: «While the ECJ appears to be confident it can distinguish between 'creating' and 'obtaining' data, the distinction is not always so easy to make. For instance, is the derivation of data from naturally occurring phenomena an act of creation or obtaining? One example may be the recording of meteorological data such as the daily maximum temperature in a particular location. Are those data created or obtained? Similarly, do scientists obtain the genetic sequences of living organisms or do they create them? The strict approach taken by the ECJ in these four cases would suggest that the answer is that such data are created. Meteorological data and genetic sequences are records and representations of natural phenomena, not the phenomena themselves, and it would be difficult for scientists to argue that they have simply collected the data as opposed to creating them. On the other hand, when a large mass of such data has been created, there are also significant costs associated with presentation and verification, which may meet the requirements in Article 7(1) of the Directive. In any event, these metaphysical distinctions will undoubtedly continue to concern courts, and commentators for some time to come».

If we arrive at, and agree with, such a conclusion, the *sui generis* right would vanish as a result, because the investment would not be entailed with the obtainment of data.

Some authors partially disagree with the precedent conclusion, arguing that in the case previously shown the substantial investment mainly goes into presenting the data in an intelligible form, rather than into starting a proper creative process. According to Derclaye, scientific data, including the genetic one, are “recorded data”, i.e. data not arbitrarily invented but simply reported as accurate as possible by man³⁹. In theory, everyone can collect them, since they pre-exist in nature, and the intellectual effort lies in the presentation of those items. So, such costs have to be considered for the evaluation of the substantial investment in the production of the database as well.

However, it should be lastly considered whether the investment is aimed at verifying or presenting the data collected in a biobank. In fact, even if we admit that the mentioned data are "created" within the interpretation of the Directive, there is another set of costs related to their presentation and verification. These costs refer to: the fact of carrying out the maintenance of the biorepository and its cryopreservation system; the supplying of them with liquid nitrogen and isopentane to keep a low temperature (-80°/170°C) for the preservation of the samples; the issue of enacting labeling machines and bar-code readers for the identification of samples; procuring instruments for the management of special types of tissues; arranging for instruments for the quality control of the samples; ordering periodical checks for the maintenance of operating standards and procedures; updating the biological samples and data with information which has become available in the meantime; updating the database platform and website; updating the protection measures required by law (these measures are highly strict, as the act of processing involves sensitive and genetic data)⁴⁰.

Since a substantial investment in verifying and presenting the data is due, biobanks are potentially eligible for the *sui generis* protection. At this point, though, it is necessary to address a further issue and make a fundamental distinction between the nature, public or private, of the biobanking.

By analyzing the operational reality of this field, we can see that the majority of biobanks are public-funded: in some cases they

³⁹ DERCLAYE, Estelle, “Databases *sui generis* right: should we adopt the spin off theory”, *European Intellectual Property Review*, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, pp. 402 ff.

⁴⁰ For more details see BARBARESCHI, Mattia y Otros, “Biobanks: instrumentation, personnel and cost analysis”, *Pathologica*, Pacini Editore, Vol. 100, Ospedaletto (Pisa), Italy, pp. 144 ff.

are a department within a public hospital, in others they are owned by universities or set up by non-profit organizations. In Europe the percentage of public-funded biobanks reaches the 97%⁴¹.

Directive 96/9/EC does not make any distinction between databases owned by a private or public entity. In some jurisdictions the *sui generis* protection is excluded for public databases⁴². Unfortunately, it is not the case of Italy, where Article 102 – bis of the national Copyright Law reproduces the ambiguity of the Directive. Nevertheless, firstly some authors and then the case law have progressively challenged this statement.

Since the beginning, Italian commentators wondered whether the *sui generis* right could be applied to public databases⁴³. In particular, an irresolvable contradiction between the industrial or commercial rationale protected by the Directive and the public goals pursued by a public administration were highlighted⁴⁴. So, according to these scholars, the *sui generis* right, at least from a strictly literal point of view, cannot work for public databases.

Furthermore, as affirmed by Dercalye: «in cases where a particular database has been made by the state, or in any case financed by the state (be it a national or local entity, and be it parliament, executive or judiciary), because of the character of its producer, irrespective of the nature of the data, and notwithstanding that a substantial investment has been made in the obtaining, verification or presentation of the data, the database should not receive protection. The arguments are close to those underlying the spin-off theory. The investment has been recouped; in other words, one should not protect the same object twice. Since the taxpayer has already paid for the data, he or she should not pay a second time. A basis for this argument is not directly apparent in the Directive but it should nonetheless be adopted. As a matter of fact, the Directive requires a substantial investment. But there is no investment, *a fortiori*

⁴¹ See ZIKA, Eleni y otros, “Biobanks in Europe: Prospects for Harmonisation and Networking”, JRC Scientific and Technical Report, European Commission, Bruxelles, Belgium, 2010, available at: <http://ftp.jrc.es/EURdoc/JRC57831.pdf>.

⁴² Namely it is the case of France and the Netherlands. DERCLAYE, Estelle, “Databases *sui generis* right: should we adopt the spin off theory”, European Intellectual Property Review, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, pp. 402 ff.

⁴³ See SPOLIDORO, Marco Saverio, “Il contenuto del diritto connesso sulle banche dati”, AIDA, Giuffrè, Torino, Italy, 1997, pp. 48 y ss.; CHIMIANTI, Laura, Banche di dati e diritto d’autore, Giuffrè, Torino, Italy, 1999; MEZZETTI, Carlo Eligio, “Banche dati e diritto *sui generis*. Alcuni profili problematici dell’attuazione della Direttiva 96/9/CE”, Quaderni di Palazzo Pepoli-Campogrande, Fondazione del Monte di Bologna e Ravenna, Bologna, Italy, 2001.

⁴⁴ CARDARELLI, Francesco, “Le banche dati pubbliche: una definizione”, Diritto dell’informazione dell’informatica, Giuffrè, Torino, Italy, 2002, pp. 321 ff.

substantial investment in "state" databases, simply because the database has been financed by the taxpayers, and since no risk has been taken, no investment has thus been made»⁴⁵.

The former (and formal) argument (i.e., the inapplicability of the *sui generis* right to public databases) has been directly confirmed by a judicial ordinance issued by the IP section of the Tribunal of Rome in 2008⁴⁶. In the case of "Poste Italiane", ruled out by the Italian Court, the national postal service was the owner of "Cerca cap" and "Cap Professional", i.e., two databases containing all the Italian postal codes. "Poste Italiane" claimed for an injunction against a publishing house in order to block the distribution of the catalogue "Codici di avviamento postale" ("Zip codes") and its CD-rom, which contained almost the same elements of "Poste Italiane" databases. The Tribunal stated that the Italian legislation (Article 102-bis L. 633/41) recognizes a right to the maker of the database consisting in the power to prohibit the extraction or re-utilization of all or a substantial part of the contents of that database; however the Court emphasized that such right belongs to the citizens or to the companies of a Member State. Since the Public Administration does not belong to these categories, it cannot be protected under the *sui generis* right and the claim of "Poste Italiane" has to be rejected.

Therefore, there are a series of doctrinal and judicial arguments that lead to the conclusion that a public biobank cannot exercise the *sui generis* right.

Then, what about private biobanks? The question can be answered once again by taking into account the reality of the biobanking rather than focusing on a hypothetical situation. As seen, the number of private biobanks in Europe is extremely scarce. Furthermore, these few examples are not exclusively aimed at offering a service of "pure" collection and preservation of data for themselves, but the databases are the biobanks' in-house resource used for the development of the biobanks' own research projects. The investments of such biobanks are not primarily addressed to the creation of a database, but the latter is generated automatically as by-products of a broader activity.

There are, thus, all the conditions for the application of the still popular "spin-off doctrine", according to which there would not be any incentive in granting a *sui generis* protection for an incidental

⁴⁵ DERCLAYE, Estelle, "Databases *sui generis* right: should we adopt the spin off theory", *European Intellectual Property Review*, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, p. 408.

⁴⁶ Tribunale di Roma, Sez. IP, ordinanza 5 giugno 2008, Edizioni Cierre s.r.l. v. Poste Italiane s.p.a.

result of other activities⁴⁷.

The criteria to filter the application of the spin-off theory in the case of “recorded data” have been effectively synthesized by Dercalyc in the following terms: «if the main activity is to present the data, the substantial investment is in collecting and presenting the data for themselves. Therefore the spin-off doctrine does not apply since there is no other activity with which the collector can recoup its investment [...] If the main activity is not to present the data but to understand the functioning of nature, be it the universe or living beings, then it can be said that the data generated are a by-product of this main activity. In this case, the spin-off theory would apply»⁴⁸.

In all the cases where there is a private biobank, this occurs because there is a company or an industry that generates the databases as a result of a more extensive research project. If the company “X” wants to find a genetic variation linked to ovarian and breast cancer, then the company will collect a cohort of biological samples and derive a set of data within a research project with the purpose to obtain a patent. In this case, the database is just a consequence, or an intermediate step, of a broader plan. Hence, since the primary activity of a private biobank is the applied research and it is not limited to the collection and presentation of the data themselves, very few and narrow spaces remain considerable for the application of the *sui generis* right.

4. Conclusion

The *sui generis* right is a very pervasive proprietary tool, which can dangerously undermine the free movement of information and the progress of knowledge. Especially in the field of biomedical research, the intense enforcement of such right may lead to a stalemate, as it restricts the access to resources of pre-competitive nature, which represent the building block for any investigation.

This risk is strongly perceived in the context of research biobanks. Their institutional goal, as internationally recognized, should be to provide resources to researchers in order to foster the understanding of human health and the disease’s molecular development. So, each restriction to such sharing should be

⁴⁷ See DAVISON, Mark /HUGENHOLTZ, Bernt, “Football fixtures, horse races and spin-offs: the ECJ domesticates the database right”, *European Intellectual Property Review*, Sweet and Maxwell, Num. 3 Vol. 27, London, UK, 2005, pp. 113 ff.

⁴⁸ DERCLAYE, Estelle, “Databases *sui generis* right: should we adopt the spin off theory”, *European Intellectual Property Review*, Sweet and Maxwell, Num. 9, Vol. 26, London, UK, 2004, p. 411.

considered in contrast with the essential aim of a biobank and, as a consequence, IPRs, included the *sui generis* right, could not be invoked.

Nevertheless, the *sui generis* protection cannot apply in this case for at least two reasons. Firstly, all the data that are collected both in the biorepository and in the electronic database are actually created by the maker of the biobank. So, according to the strict interpretation given by the ECJ, the substantial investment done in this phase cannot be eligible for a *sui generis* protection.

Secondly, even assuming that such data are not created and that a biobank invests substantially at a later stage which is exclusively related to the verification or presentation of the data, however, the *sui generis* right could not be applied. Public biobanks, in fact, cannot be protected on the basis of both a formal and an economic argument: on the one hand, a public biobank cannot be considered as citizen or companies of a Member State in compliance with the Directive's provisions; on the other hand, the activity pursued by public administration entails no commercial risk by definition, and thus, considering the rationale of the Directive, there is no incentive in order to protect any investment. Furthermore, the *sui generis* right cannot apply to private biobanks: their databases are not a primary activity, and, applying the spin-off doctrine, they do not benefit of any type of protection.

In conclusion, the "terrible" *sui generis* right is unable to damage the data sharing in the biobanks' framework. Indeed, none of the makers of a database can legally enforce such a right. However, this does not mean that this area is free from obstacles to the knowledge's access: the crucial issue, which has still to be solved by lawyers, refers to the restrictions on the access of knowledge, which are imposed by contracts, by the licensing and the technological measures.

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