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«PROPERTY PARADIGM» AND PROTECTION OF RIGHTS CONCERNING GENETIC INFORMATION

Abstract: The article analyses the current legislation relevant to the use of genetic information, with reference to persons, plants and animals. The legal sources (at International, supranational, national levels) deal with the issue to protect some important interests as the dignity of the person, in the case of human genetic information, or the protection of the environment. The norms use a "proprietary paradigm" with the aim of putting genetic information under the control of their owner, which are the individual or the State. The proprietary paradigm is expressed through the consent of the interested persons, which is required for the use of their genetic information and, on the other hand, through the notion of sovereignty of the State on the genetic resources of the environment.

Summary: 1. Legal discipline of genetic information concerning persons, animals and plants. – 2. Genetic information and «proprietary paradigm». – 2.1. Human genetic information and privacy protection. – 2.2. Sovereignty over natural resources. – 3. Critical aspects of proprietary paradigm. – 3.1. Consent and rights of relatives. – 3.2. Rights of Indigenous Communities and Other Rights on Genetic Resources. – 4. Property as insufficient scheme for genetic information. – 5. From the proprietary paradigm to fundamental rights. – 6. Genetic information and balance between fundamental rights. The case of the research activities. – 6.1. Research and other activities on the personal genetic information. – 6.2. Research concerning genetic resources. – 7. Civil enforcement of rights concerning genetic information.

1. — *Legal discipline of genetic information concerning persons, animals and plants.*

The interest of law for genetic «data» or «information» concerning

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persons, animals and plants is growing(1).

The genetic information, which is present in cells of all living beings, establish the features of the individuals which may be transmitted from a generation to the subsequent ones.

This interest has been growing since the manipulative power of techno-science has allowed not only to know the meaning of genetic information(2), but also to use it and to intervene in the structure of life (through techniques like as cloning or genetic editing).

The law disciplines the rights and duties concerning genetic information depending on the kind of live beings and thus on the interests to be protected(3).

A) Genetic information of the persons

Article 1, of the Recommendation of the Committee of Ministers of Council of Europe, No. R (97) 5 on the Protection of Medical Data (of 13 February 1997) put the genetic information among the «medical data», that's to say the «personal data concerning the health of an individual». In particular the genetic data are defined in very huge terms(4) as «data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals»(5).

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(1) In particular: «Data represents material for analysis. Information is what fallows from that analysis. The significance of the data that we perceive is it is interpreted», see M. Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, Cambridge, 2012, p. 56.

(2) An important milestone of the history in this sector has been the *Human Genome Project* started on and put in place by US public body, *National Institutes of Health* (NIH), and a private undertaking, *Celera Corporation* established and run by the biochemist Craig Venter.

(3) See J. Gerards, *General Issues concerning Genetic Information*, in J.H. Gerards, A.W. Heringa, H.L. Janseen, *Genetic Discrimination and Genetic Privacy in a Comparative Perspective*, Oxford, 2005, pp. 5-11.

(4) See C.S. Diver, J.M. Cohen, *Genophobia: What Is Wrong with Genetic Discrimation?*, in *U. Pa. L. Rev.*, 2001, 149, p. 1451.

(5) The «International Declaration on Human Genetic Data» of 2003 of UNESCO (hereinafter «Declaration of UNESCO»), distinguishes (at Article 2) human genetic data, which are «Information about heritable characteristics of individuals obtained by analysis

The topic is also disciplined by the European Convention on Human Rights and Biomedicine (approved by the Council of Europe in 1997 in Oviedo), Chapter IV, on the Human Genome and its Additional Protocols (6).

Within European Union law, the Charter of Fundamental Rights explicitly refers to genetic information in some provisions, such as Articles 3 and 21.

The genetic information concerning natural persons are considered as an important expression of the personality of the individual and, from a legal point of view, as object of the fundamental rights. They may be collected during therapeutic and scientific research (7).

The Convention on Human Rights and Biomedicine signed in Oviedo on April 4, 1997 concerning the human genome, establishes, above all the prohibition of discriminations based on the genetic heritage (Article 11) and of the interventions on genome aiming at introducing modifications in the genome of any descendants (Article 14).

On the other hand, EU Charter reaffirms the prohibition of discrimination based, among others, on genetic characteristics (Article 21) and imposes the ban of the eugenic practices, in particular those aiming at the selection of persons, as well as the reproductive cloning of human beings.

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of nucleic acids or by other scientific analysis», the «human proteomic data» («Information pertaining to an individual's proteins including their expression, modification and interaction»), and, more in general the «biological samples», concerning «Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual».

(6) Varios protocolos adicionales a la Convención de Oviedo hacen referencias a la información genética como por ejemplo: el Protocolo de 1998 relativo a la prohibición de la clonación humana; lo de 2001, relativo al trasplante de órganos y tejidos de origen humano; el Protocolo de 2005 relativo Investigación Médica Aplicada al hombre, y por último el más reciente, que es también la más interesante para este trabajo, que el Protocolo Adicional a la Convención de Oviedo relativo a las pruebas genéticas para la salud adoptada en Estrasburgo el 27 de noviembre de 2008.

(7) More correctly, «Data represents material for analysis. Information is what fallows from that analysis. The significance of the data that we perceive is it is interpreted», see M. Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, Cambridge University Press, Cambridge, 2012, p. 56. Anyway the Directive 96/45/EC (see Article 2, letter a) uses data as information: «"personal data" shall mean any information relating to an identified or identifiable natural person ("data subject")».

At national level, usually the Constitutions do not explicitly regulate the rights concerning the genetic data of persons.

Only some Constitutions recently amended, such as the Swiss (see Article 24-*nonies*) and the Portuguese (see Article 26.3, par. 2) ones, make specific reference to the protection of the genetic data.

Usually the legal issues concerning genetic information are regulated at the legislative level, as in the case of the laws of France and Austria(8), and other legislations(9).

Other countries, such as Italy, use soft law instruments as guidelines and recommendations of the Ethics Committees(10).

Based on the briefly mentioned legislation, the protected interests in the case of people genetic information, are at least two.

First, genetic information is considered a particularly important component of personality, and therefore its use must respect the dignity(11) of individuals and in general their fundamental rights(12).

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(8) In particular, the French Law regulates the use of the genetic data, through the Chapter III of the Title I of the Civil Code devoted to «De l'examen des caractéristiques génétiques d'une personne et de l'identification d'une personne par ses empreintes génétiques» (examining the genetic characteristics of a person and the identification of a person using genetic prints), which was introduced by the laws concerning bioethics, the last one being the Law no. 2011-267 of the 14 March 2011. About the French *loi de bioétique*, see R. Cippitani, *Principi e metodo nella revisione della normativa francese relativa alla bioetica*, in *Dir. fam. e pers.*, 2012, pp. 1836-1865; Id., *La nueva ley Francesa en tema de bioética en el contexto europeo*, in *Criminogenesis*, 2011, pp. 199-214.

(9) With respect to the Swiss Law, see the Federal Law on Human Genetic Testing, approved on 2004 and entered into force on 1st April 2007. In Germany in the last years a Law concerning the Genetic Diagnostic has been approved (*Gendiagnostikgesetz* - GenDG), and entered into force on 1st February 2010. See A. Diurni, *Esperienze di regolamentazione della diagnostica genetica*, in *Danno e resp.*, 2010, p. 660.

(10) According to Italy, see the document of the Comitato Nazionale per La Bioetica, *Orientamenti bioetici per i test genetici*, of 19 November 1999 and «Linee-guida per le attività di genetica medica» enclosed to the Agreement between Italian Ministry of Health and Regions of 15 July 2004.

(11) A. Falcone, *La tutela del Patrimonio Genetico Umano, fra Costituzione e Diritti. Verso la formazione di un Corpus Iuris sul genoma umano*, Catanzaro, 2012, p. 17.

(12) A. Ruggeri, *"Nuovi" Diritti fondamentali e tecniche di positivizzazione*, in *Pol. dir*, 1993, 2, p. 183.

In particular, the protection of dignity is aimed at preventing or punishing discrimination based on genetic characteristics (Article 11 Oviedo Convention and Article 21 of the EU Charter). On the other hand, eugenic practices, in particular those aimed at the selection of persons, as well as the reproductive cloning of human beings (Article 3 EU Charter) are also prohibited.

Another interest taken into consideration does not concern the person but the humankind. It is the intangibility of the human genome. In fact, the modifications of hereditary genetic are prohibited (see UN Declaration on the Human Genome and Article 13 Oviedo Convention; see also Article 57, new Argentine Civil Code, which prohibits all practical, scientific and therapeutic practices which are aimed at the genetic alteration of the human embryo that can be transmitted to their offspring).

B) Genetic information and biodiversity

With reference to the plants and animals, the international instruments (Convention on Biological Diversity, hereinafter referred to as «CBD») define the «biological resources» which include «genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity».

In particular, «genetic resources» are defined as genetic material of real or potential value. On the other hand, «genetic material» means any material of plant, animal, microbial or other origin which contains functional units of heredity.

With respect to the genetic information on plants and animals, the interest of legal sources is linked to the protection of the environment(13).

In the recent years, the destruction of natural biodiversity, caused by the spreading of more profitable crops or animals for companies, has begun to be considered a threat to the planet, and to humans.

This situation has led to the adoption, since, the 1990s of international

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(13) Cfr. E.O. Betanzos Torres, *Medio ambiente*, in M.I. Álvarez Ledesma, R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, Roma-Perugia-México, 2013, p. 432 ff.

instruments such as the above mentioned CBD of 1992 approved by United Nations; The Nagoya Protocol on «Access to genetic resources and the fair and equitable sharing of benefits arising from their use of the Convention on Biological Diversity» (hereinafter referred to as the «Nagoya Protocol») entered into force in 2014; The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted in 2001.

At national and supranational levels, other legal texts implement the international instruments. For example, the European Union has issued the Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

Many other international, supranational and national laws may be applicable to discipline the interests linked to the genetic of persons as well of the other living beings.

2. — *Genetic information and «proprietary paradigm».*

The legal sources, which protect directly the interests associated with the genetic information of people and other living beings, are obviously recent.

At the same time, the legal mechanisms put in place owe much to old legal concepts.

The cited rules, and others ones dealing with the matter of genetic information, seem to be built around a «proprietary paradigm».

In fact, expressions such as «heritage» are used to refer to the human genome, albeit in a «symbolic» way (see Article 1 of the UNESCO Declaration on the Human Genome) (14).

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(14) This arises from the work of the Pandectistic, especially in Savigny (see his *System des heutigen römischen Rechts*), which is the ground on which the Civil Codes of the continental Europe were elaborated. According to the Civil Code, the patrimony of a person is a set of obligations and rights on things.

«Genetic heritage» also appears in documents dealing with natural genetic resources (15).

Within other legal sources, it is possible to find the references to the «genetic patrimony» (16).

Indeed, beyond the terminological aspects, the proprietary paradigm influences the definition and protection of the interests associated with genetic information.

2.1. – *Human genetic information and privacy protection.*

In the case of human genetic information, the main instrument used to protect the interests of people is the privacy discipline.

At European level, the first regulatory intervention in this area was launched in 1981 by the Council of Europe with the Convention n. 108, which was put in place in the same year by the Council of Europe with the Strasbourg Convention on the Protection of Individuals with regard to Automatic Processing of Personal Data.

Subsequently, the European Union law has regulated the matter by means of the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The Directive did not refer to genetic information, but rather to «sensitive» personal data that may reflect racial or ethnic origin, and to health-related data (Article 8, par. 1).

The classification of genetic information as a sensitive personal data was confirmed by literature (17) and by documents such as the «Working

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(15) See, for example the use of the term «patrimony» in the document T. GREIBER et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*, IUCN Environmental Policy and Law Paper No. 83, Bonn, 2013.

(16) See also some national laws, such as the Brazilian Lei n° 13.123, of 20 May 2015, providing that «dispõe sobre o acesso ao patrimônio genético, sobre a proteção e o acesso ao conhecimento tradicional associado e sobre a repartição de benefícios para conservação e uso sustentável da biodiversidade».

(17) M. D'AMICO, *Il trattamento pubblico dei dati sensibili: la disciplina italiana a confronto con il modello europeo*, in *Il diritto comunitario e degli scambi internazionali*, Vol. 4, 2002, p. 817 ff.

Document on Genetic Data» (see par. III, p. 5), adopted on 17 March 2004 by the «Article 29 Data Protection Working Party», an advisory body of the European Commission(18).

Finally, this qualification has been formally established by the new Regulation (EU) 2016/679 which will replace the Directive 96/44/EC of 28 May 2018(19).

As a consequence of the qualification as «personal data»(20), genetic information must be subject to the control of the holder. This is expressed mainly through the obligation to require the consent of the concerned person by the controller(21).

According to the definition contained in Article 2 of the UNESCO Declaration, which has been mentioned above, consent is the «specific, informed and express permission that a person freely gives for his genetic data to be collected, processed, used and preserved » (see also Article 4, no. 11 of Regulation (EU) 2016/679 or Article 2 (j) of Directive 2001/20/EC on clinical trials)(22).

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(18) Available at *http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91_en.pdf.*

(19) Regulation (EU) 2016/679 of the European Parliament and of The Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

(20) See Article 4, no. 1, of the Regulation which states that the personal data are any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person». The genetic information of natural persons are considered as «sensitive data» (see Article 9, parr. 1 and 4).

(21) About the informed consent to use genetic information of the persons see R. Cippitani, *Consent to the Use of Genetic Information: Between Respect of Privacy and Protection of Other Fundamental Interests*, in *Diritto e Processo/Right and Remedies/Derecho y Proceso*, 2014, pp. 493-532.

(22) See A. Sassi, *Derechos patrimonialmente neutros*, in M.I. Álvarez Ledesma, R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica (en el ordenamiento civil)*, rif., p. 213 ff.

Consent derives from a «proprietary»(23) and individualistic(24) logic concerning the whole human body and its parts, including genetic data.

As matter of fact, the proprietary is at the base of the meaning itself of «privacy», since the origin of the notion can be find in the famous work of Samuel Warren and Louis Brandeis, «The Right to Privacy», Published on Harvard Law Review on 1890. In that paper the notion of privacy was drawn up within the proprietary paradigm, even if from a «spiritual» and not «physical» viewpoint.

2.2. – *Sovereignty over natural resources.*

With respect to international legal instruments dealing with biodiversity, the proprietary logic is affirmed through the «sovereignty» of States over natural genetic resources.

As matter of fact, sovereignty, as power over everything within national borders, is still understood as a kind of property, as Grotius understood it in his *De iure belli ac pacis*.

This approach is clearly showed by CBD (Article 15, par. 1) and may be found in other international instruments, especially in the ITPGRFA (Article 10.1) and in the Nagoya Protocol.

In particular Article 15, par. 1, CBD states that «Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation».

The affirmation of the sovereignty of States over genetic resources can be considered as a fundamental principle of international law, since it arises from the 1972 Stockholm Declaration («Declaration of the United Nations Conference on the Human Environment»)(25) and has been confirmed by the «Rio Declaration on Environment and Development» of 1992.

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(23) See for example J. de Witte, H. Have, *Ownership of genetic material and information*, in *Soc. Sci. Med.*, 1997, July, 45(1), pp. 51-60.

(24) See, Working Party, Working Document on Genetic Data, p. 8

(25) See the principle no. 21: «States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own

Also in the preamble to the United Nations Framework Convention on Climate Change, it is recalled that the «States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies» and reaffirms «the principle of sovereignty of States in international cooperation to address climate change».

This assertion of sovereignty is coherent with the model of international law governing relations among autonomous and independent States(26), which have the final say i on the internal application of transnational rules(27).

3. — *Critical aspects of proprietary paradigm.*

The use of notions linked to the idea of property to regulate the subject of genetic information allows to achieve some important results.

As far as human genetic data are concerned, this approach is justified by the attempt to protect people from the enormous risks deriving from the massive use of techno-science.

In the case of sources referred to natural genetic resources, the affirmation of State sovereignty has been the response to the depredation of natural resources by developing countries, which began in colonial times and is continued nowadays by the multinationals(28).

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resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction».

(26) Among the definition of «international law», see B. Conforti, *Diritto internazionale, Napoli*, 2010, p. 3 ff.; C. Rosseau, *Derecho internacional público,* Barcelona, 1996, p. 1 ff.

(27) How Henkin argues: «almost all nations observe almost all principles of international law and almost all of the obligations almost all the time» (L. Henkin, *How Nations Behave*, New York, 1979). However, «it is sometimes violated with impunity» (J.L. Goldsmith, E.A. Posner, *The Limits of International Law*, New York, 2005, p. 13; see also A.T. Guzman, *How International Law Works. A Rational Choice Theory*, New York, 2008).

(28) See also the affirmation of sovereignty by the Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property 1970, which introduced the notion of «cultural property».

However, the proprietary paradigm does not allow to solve many of the legal problems that refer to the genetic information.

A critical aspect of the proprietary approach is the admissibility of patents for biotechnological inventions (29).

The commodification of genetic information, which is done through industrial law, can affect the fundamental interests mentioned above (30).

Another series of criticisms of the proprietary paradigm applied to genetic information derives from the opposition between the rights of the owners (the person, the State) and the non-patrimonial rights of other subjects.

3.1. – *Consent and rights of relatives.*

The case of the genetic data of people appears particularly interesting.

The «proprietary» conception of privacy, expressed by the power of the holder to oppose against the intervention of the others, may conflict with the characteristics of genetic data (31).

Particularly noteworthy are the issues arising from the «familiarity». The genetic information are unique and distinguish~~es~~ an individual from other individuals, but at the same time reveal~~s~~ information about (and has implications for) other people, i.e. biological relatives (see *Working document on privacy*, par. III) (32).

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(29) About the legal issues concerning the patents on biological invention, see among the others, N. Lucchi, *Understanding genetic information as a commons: from bioprospecting to personalized medicine*, in *International Journal of the Commons*, Vol. 7, no 2 August 2013, pp. 313-338.

(30) S. Vezzani, *Le risorse fitogenetiche per l'alimentazione e l'agricoltura nel dibattito sui «global commons»*, in *Riv. crit. dir. priv.*, 2013, pp. 433-464; with reference to the rights of the indigenous communities, see H. Pacheco Cornejo, *Propiedad Intelectual en la integración de Chile a los mercados internacionales. El desafío de la preservación de los derechos indígenas sobre su patrimonio intangible*, in M.I. Álvarez Ledesma, R. Cippitani, *Derechos Individuales e integración regional (Antología)*, ref., p. 599 ff.

(31) M. Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, ref., 2012, *passim*.

(32) See M. Taylor, *Data Protection, Shared (Genetic) Data and Genetic Discrimination*, in *Med L. Int'l*, 2006, p. 51.

As matter of fact, genetic data may show kinship and family ties, ethnicity, predisposition to diseases, and other characteristics common to members of the biological family.

As a consequence, the discipline of informed consent does not allow, for example, to solve the ethical dilemma of a physician or other health professional, who, when examining the biological material of a person, realizes the risk of a genetic disease: on the one hand, the doctor is bound by the obligation of professional secrecy, as well as the right not to know the person concerned; on the other hand this situation could affect the members of the her/his biological family.

According to the above mentioned «Working document on privacy» the other members of the same genetic family would have to be protected.

In accordance with Article 18 of the Additional Protocol to the Oviedo Convention on Genetic Testing, when the results of a genetic test performed on a person may be relevant for the health of other family members, the person concerned should be informed.

However, the consequences and conditions of such information are unclear.

Article 15, par. 1, lett. g) of Regulation (EU) 2016/679 states that the person responsible for the processing of personal data must inform the person concerned, even when the information derives from another source than the person concerned. But this provision is likely to apply only when there is a direct relationship between the responsible (in this case the health care professional) and the genetic relative (person concerned).

Anyway, in this case too, there is no solution to the problem of conflict with the professional secrecy.

3.2. – *Rights of Indigenous Communities and Other Rights on Genetic Resources.*

Other problems arises in the field of genetic resource discipline, where the proprietary paradigm, which manifests itself through the sovereignty of the State, does not consider some other important rights.

In fact, international treaties on genetic resources provide for the protection of the rights of indigenous communities present in particular territories (see for example Article 2 of the Nagoya Protocol)[33], but there are no clear mechanisms through which the State should protect those rights.

Some elements can be inferred from other international instruments such as Convention no. 169 of the International Labour Organization on «Convention concerning Indigenous and Tribal Peoples in Independent Countries» of 1989, which states in article 15 that «The rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded».

These provisions provide the right of indigenous peoples to participate in the use, management and conservation of natural resources and to be involved through consultative or participatory procedures by the State. But the State itself will have to adopt specific measures that comply with the Convention.

On the other hand, the principle of sovereignty is not always consistent with the objective of protecting the environment and biological diversity, since it is not an issue that can be limited to a particular State.

In general, in the case of people, or of natural resources, the proprietary paradigm may represent an obstacle to the achievement of other important objectives of the community, such as scientific research or public health.

There are rules that, for example, recognize these interests, but always in the respect of state sovereignty.

For example, research on genetic make-up and/or biochemical composition of genetic resources is considered particularly relevant in the Nagoya Protocol, and Article 8 provides that each State shall «create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research» (see also the recitals 6, 18, 27, 28, and the Article 13 of the Regulation (EU) No 511/2014 of the European

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[33] Cfr. H. Pacheco Cornejo, *Conocimientos tradicionales*, in M.I. Álvarez Ledesma, R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, ref., p. 67 ff.

Parliament and of the Council of 16 April 2014 concerning «compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union»).

However, any decision on measures allowing scientists to use genetic resources is left to States. In particular each legal system gives its own interpretation to concepts such as «research» and «non-commercial research»(34).

This is particularly true in a subject such as science, where «national interests», even the military ones, are generally considered superior to the more general interests of humanity(35).

4. — *Property as insufficient scheme for genetic information.*

Another problem is that ownership as a legal instrument is not the correct legal framework to understand the rights over genetic information.

This not only because of the material content associated with the concept of property itself by the Civil Codes, which refer to the right

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(34) According to the EU law, for example, see the definitions provided by European Commission, Communication, Framework for state aid for research and development and innovation, C(2014) 3282, of 21 May 2014. As argued by E. Chege Kamau, *Research and development under the Convention on Biological Diversity and the Nagoya Protocol*, in E. Chege Kamau, G. Winter, P.-T. Stoll (edited by), *Research and Development on Genetic Resources Public Domain Approaches in Implementing the Nagoya Protocol*, London, 2015, pp. 70-124, being the term «research» not defined, it will be needed to make reference to the Article 31(1) of the Vienna Convention on the Law of Treaties, which establishes that the terms have to be interpreted in good faith with the ordinary meaning in their context and in light of the treaty's object and purpose (p. 74).

(35) In correspondence with the rise of the National States, science and teaching became powerful tools to build the idea of nation and nationality. For example, Wilhelm Von Humboldt in his «*Über die innere und äußere Organisation der höheren wissenschaftlichen Anstalten in Berlin*» («On the internal and external organization of the high scientific institutions in Berlin») of 1810 underlined the role of the universities and other scientific institutions to shape the spiritual and moral culture of a Nation.

to enjoy and dispose of a thing (see Article 348 (1) Civil Code; Article 842 Italian Civil Code, Article 333 of Spanish Civil Code; see also the Article 810 of Italian Civil Code concerning the legal notion of «good» as a «thing»).

Beyond that, it is difficult to frame the characteristics of genetic information in the realm of the traditional notion of property.

In particular, the doctrine has sought to identify the category of rights established by international texts with respect to natural resources. But without a satisfactory result.

As Bromley observes (36), legal property regimes are usually four: state ownership («In a state-owned regime, ownership and control over use rests in the hands of the state»); individual property; common property regime (an identifiable group of individuals, such as indigenous or traditional communities), and non-proprietary (open access) regimes.

Rights over genetic resources do not appear to be consistent with any of the above-mentioned regimes.

Sovereignty over natural resources does not mean that the country must nationalize them and that, therefore, genetic resources must be part of the State's heritage.

On the other hand, the discipline of international sources is not incompatible with private or community use.

However, private or community property must take into account the power accorded to States by international instruments.

Nor it seem correct to consider that the discipline of international treaties establishes «open access» (37), meaning «open access» as «res nullius» (38) of natural resources.

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(36) See D.W. BROMLEY, *The Commons, Common Property, and Environmental Policy*, in *Environmental and Resougce Economics*, 2, 1992, pp. 1-17.

(37) M. OKSANEN, *Privatising Genetic Resources: Biodiversity, Communities and Intellectual Property Rights*, in J. BARRY, M. WISSENBURG (ed.), *Sustaining Liberal Democracy. Ecological, Challenges and Opportunities*, London and New York, 2001, pp. 135-148.

(38) D. W. BROMLEY, *Common property as metaphor: systems of knowledge, resources and the decline of individualism*, in *The Common Property Resource Digest*, n. 27, 1993, pp. 1-8.

Thus, it does not appear that international legal sources on natural resources choose or establish a specific proprietary regime.

In fact, the sources provide some limits to national legal disciplines, in order to achieve the objective of protecting biodiversity and avoiding excessive exploitation of the resources of developing countries.

Within this framework, any type of national regime is compatible if it complies with international standards.

5. — *From the proprietary paradigm to fundamental rights.*

As above mentioned, proprietary logic is not adequate to deal with the issue of genetic information legally.

As matter of fact, in the case under consideration, as in other areas, the «terrible right» (as Stefano Rodotà has called property) (39) in the last decades has changed profoundly.

Within national constitutions and international instruments, property is no longer an absolute power over a material thing. This is because the objects of rights are often immaterial and, above all, because the right to property is recognized from the perspective of its social function (see, for example, Article 42 of the Italian Constitution), i.e. as a tool for implementing interests that go beyond those of the owner.

In addition, the property itself is considered as a fundamental right (40).

This evolution of the right of property is well observed in the jurisprudence of the regional Courts.

In this sense, the European Court of Human Rights protects all legal property recognized by law, regardless of whether it is a material good and whether the subjective legal situation can be considered property in the traditional sense.

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(39) See S. Rodotà, *Il terribile diritto. Studi sulla proprietà privata*, Bologna, 1990.

(40) M. Paradiso, *Propiedad (Perfiles de derecho supranacional)*, in M.I. Álvarez Ledesma, R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, ref., p. 543 ff.

Another interesting case is the right to property (see Article 21 of the American Convention on Human Rights), developed before the Inter-American Court of Human Rights, for example in the Yakye Axa Indigenous Community v. Paraguay case(41).

According to that jurisprudence, the Court affirms that «property» – a in this specific case the right of indigenous peoples over «ancestral» territories – is the means for the protection of the human rights of members of the indigenous community.

As the Court recognizes, it is «a land right different from the general concept of private property law»(42). In contrast, property, as a human right, is a set of aspects of material elements and also of intangible components, political, symbolic, cultural.

Scholars highlight the insufficiency of the traditional idea of property, based on the exclusion of others from the enjoyment of material goods and scarps. This notion is not adequate to understand and regulate the phenomena of an age, such as the present one, characterised by immaterial goods that can be products, shared and used at the same time by an infinite number of subjects. This has been defined as the «age of access», as opposed to the previous «age of ownership»(43).

Also the concept of sovereignty, within the so-called «global constitutionalism»(44), has changed its meaning. The exercise and protection of fundamental rights is, in fact, the first priority of the State(45) and the new justification of political power(46).

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(41) Corte IDH, judg. 17 June 2005, *Comunidad indígena Yakye Axa/Paraguay*, Series C No. 25. See the commentary by L. CASSETTI, *Il diritto di «vivere con dignità» nella giurisprudenza della Corte Interamericana dei diritti umani*, in *www.federalismi.it*, 15 December 2010, esp. p. 7.

(42) Corte IDH, *Comunidad indígena Yakye Axa/Paraguay*, ref., par. 121.

(43) J. RIFKIN, *Era del acceso. La revolucion de la nueva economia*, trans. of The Age of Access, Barcelona, 2000.

(44) L. FERRAJOLI, *Más allá de la soberanía y la ciudadanía: un constitucionalismo global*, in M. CARBONELL, R. VÁZQUEZ, (eds.), *Estado constitucional y globalización*, México, 2001, pp. 313-318.

(45) A. E. PÉREZ LUÑO, *Los derechos fundamentals*, Madrid, 1991, p. 19.

(46) Cfr. J. RAWLS, *A Theory of Justice*, Cambridge, Massachusetts, 1980, pp. 4-7.

Therefore, as property is the fundamental right and instrument for implementing other fundamental rights, it must be applied consistently with the constitutional system and with the international human rights law.

The link between property and human rights has been confirmed in the recent years in the theory of «commons»(47), which seeks to protect some «goods» which, regardless of being the object of rights of individuals, must be able to be used by all humanity, such as water, air, and, in general, the environment.

Access to and enjoy of such property is considered as a fundamental right.

Genetic information can be considered as common goods, since, as seen above, they are associated with interests that are not those of a particular State or individual.

6. — *Genetic information and balance between fundamental rights. The case of the research activities.*

If rights to genetic information are fundamental rights, they are not absolute rights and must be balanced with other ones.

6.1. – *Research and other activities on the personal genetic information.*

As it has been stated in relation to the genetic heritage of the person, ethics should not be reduced to the autonomy of the person and autonomy should not be limited to the ownership of the data. The reduction of ethics to the property would have a high price: not to take into account the distributive justice and the optimization of the social results(48).

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(47) About the commons, see, among others, A. Palazzo, *Cittadinanza, ambiente e costituzione dei beni comuni*, in *Diritto e processo*, 2012, p. 217 ff.; M.R Marella (ed.), *Oltre il pubblico e il privato. Per un diritto dei beni comuni*, with the introduction of S. Rodotà, Verona, 2012; U. Mattei, *Beni comuni*, Roma-Bari, 2011.

(48) P.Taylor, *When consent gets in the way*, in *Nature*, 6 November 2008, vol. 456, pp. 32-33.

For example, restrictive policies on access to genetic information(49), limiting it in the name of the rights of the owner or of the State, have a negative impact on scientific research and, consequently, on the solution of problems affecting human health or protection of the environment(50).

Privacy should be coordinated with other freedoms or rights recognized as relevant by constitutional and transnational rules, such as freedom of inquiry (see, for example, Article 13 of the Charter of Fundamental Rights of the European Union)(51).

Anyway, it is already possible to find principles capable of establishing a balance between the rights of holders of genetic information and other fundamental interests.

For example, Article 26 of the Oviedo Convention permits restrictions to the consent, if such restrictions are provided for by law and if they constitute necessary measures, in a democratic society, for public safety, prevention of criminal offenses, protection of public health or of the rights and freedoms of others(52).

From the methodological point of view, it would be advisable, also in relation to the balance of the different interests, to implement diverse strategies and new legal instruments(53).

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(49) W. W. LOWRANCE, F. S. COLLINS, *Identifiability in Genomic Research*, in *Science*, 3 August 2007, vol. 317, pp. 600-602.

(50) Cfr. M.A. GYMREK, L. MCGUIRE, D. GOLAN, E. HALPERIN, Y. ERLICH, *Identifying Personal Genomes by Surname Inference*, in *Science*, vol. 339, 18 January 2013, pp. 321-324.

(51) See C.F. MOLINA DEL POZO, C. ARCHONTAKI, *Libertad de artes y de Investigación Científica, Libertad de Cátedra*, in M.I. ÁLVAREZ LEDESMA, R. CIPPITANI (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, ref., 2013; R. CIPPITANI, *La libertad de cátedra y de investigación en el ámbito de la autonomía universitaria*, in A.F. Buenrostro Ceballos, *La libertad de cátedra y de investigación en el ámbito de los derechos humanos*, Mexicali, 2015, pp. 129-188.

(52) R. ANDORNO, *The right not to know: an autonomy based approach*, en *Journal of Medical Ethics*, 2004,30, pp. 435-440, esp. p. 437. With respect to the conditions and the limitations of the human rights, see also M.I. ÁLVAREZ LEDESMA, *La libertad de expresión en el sistema electoral mexicano desde una perspectiva jurídica*, in G. LÓPEZ MONTIEL, E. TAMÉS MUÑOZ (coord.), *Libertad de expresión en el proceso electoral 2012*, México, PNDU/ONU, 2013.

(53) See L. VILLANI, *Biobanche e test rivelatori di informazioni genetiche: spunti di riflessione per un nuovo consenso informato*, in *Resp. civ.*, 2010, 2, p. 140.

In the case of genetic data of the person, which should also be considered as a common good(54), consent should not be considered as a rigid and monolithic form of opt-in/opt-out but, on the contrary, a set of legal instruments to protect the interests of the «owner», other people and humanity as a whole.

Therefore, techniques can be used which provide that the consent of a person is normally necessary and sufficient, with the exception of cases in which the interests of others must be taken into account(55).

The above considering that not all information has the same value to protect each individual's own interests(56) and that sometimes the only consent is not a guarantee for the protection of the person, especially in the case of asymmetric relationships(57).

In order to avoid abuses, independent authorities, organizations and ethical committees should be involved to ensure a balance between interests and fundamental rights (see Article 6, paragraph 3, of Directive 2001/20 / EC).

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(54) See the document «Ethical, legal and social aspects of genetic testing: research, development and clinical applications» of 2004 released by a committee of experts for the European Commission, DG Research, p. 41 ff., in particular p. 42.

(55) See the French legislation, in particular Law no. 814/2011, providing a specific function of the physician and of the national Agency of Biomedicine in the communication of the genetic information to the familiars of the patient (see Article L.1131-1-1 of Code de la Santé Publique).

(56) See, for example, International Committee of UNESCO, «*Human Genetic Data: Preliminary Study by the IBCon its Collection, Processing, Storage and Use*» of 15 May 2002, which states that «Many tests which reveal genetic information will not have a great deal of significance for the person tested (…). Other tests, however, will have major implications, both for the individual and for relatives. The principle stated above sets out the consent requirements. For practical reasons, it would be unrealistic and unnecessary to require that there be specific consent to the genetic component in any test unless the consequences of this are sufficiently serious enough to justify this» (par. 59, p. 15).

(57) See the solutions proposed by the European Group on Ethics in Science and New Technology, Advise no. 18 concerning the «Ethical Aspects of Genetic Testing in the Workplace» of 2003, par. 2; see also the above – mentioned document «Ethical, legal and social aspects of genetic testing: research, development and clinical applications» of 2004.

6.2. – *Research concerning genetic resources.*

Similarly, legal discipline for the protection of natural resources should be applied in such a way that the State's power over genetic resources (sovereignty) is not arbitrary, but is aimed at the protection and balance of all protected interests: the interests of the State, of the local traditional communities, of landowners; the rights deriving from creative activities such as patents, as well as general interests (protection of biodiversity, scientific research).

In fact, as stated in relation to the EU discipline that incorporates the Nagoya Protocol (see Regulation (EU) No 511/2014), international, supranational and domestic standards must also respect principles such as solidarity, which protect the weakest individuals or communities (58).

The international sources themselves set out that benefits «arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention» (Article 5, par. 1, Nagoya Protocol, see also Article 15, parr. 3 and 7 of the CBD). Where benefits are not only represented by a monetary compensation, such as fees, royalties, co-ownership (see Annex to the Nagoya Protocol), they may consist also in the participation in collaborative cultural activities such as: (a) Sharing of research and development results; (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources; (…) (d) Collaboration, cooperation and contribution in education and training; (e) Admittance to ex situ facilities of genetic resources and to databases; (f) Transfer to the

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(58) V. Colcelli, *A Critic Lecture of the EU Two Faced Approach to Biodiversity: Equal Guaranty or Multinational Bio-Raid? The Importance of a Self-Reconsideration of EU Politics in Biodiversity*, in G. Cerrina Feroni, T.E. Frosini, L. Mezzetti, P.L. Petrillo, (edit by), *Ambiente, Energia, Alimentazione Modelli Giuridici Comparati Per Lo Sviluppo Sostenibile (Environment, Energy, Food Comparative Legal Models For Sustainable Development)*, Firenze, 2016, vol. I, p. 41 ff.

provider of the genetic resources of knowledge and technology under fair and most favourable terms, including ~~on~~ concessional and preferential terms where agreed, in particular knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; (g) Strengthening capacities for technology transfer; (h) Institutional capacity-building; (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations; (j) Training related to genetic resources with the full participation of countries providing them and, where possible, in such countries; (k) Access to scientific information relevant to the conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies; (l) Contributions to the local economy; (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing them; (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; (o) Food and livelihood security benefits; (p) Social recognition; (q) Joint ownership of relevant intellectual property rights.

Furthermore, it should be also important to prefer more adequate interpretations of terms such as «research» or « non commercial research» used, but not defined, within the legal sources protecting the genetic resources.

With that respect, in order to interpret the difference among «non-commercial» and «commercial» research, it should be preferred a «functional» definition concerning the availability of the results of research (59). «Non-commercial research» would be the research which makes available its results to the public without restrictions, in order to disseminate and improve the base of knowledge concerning the genetic resources.

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(59) According to C. von Kries, G. Winter, *Defining commercial and non-commercial research and development under the Nagoya Protocol and in other context*, in E. Chege Kamau, G. Winter, P.T. Stoll, (eds.), *Research and Development on Genetic Resources. Public domain approaches in implementing the Nagoya Protocol*, London-New York, 2015, pp. 125-147, esp. p. 131 ff.

On the contrary, other definitions based on formal viewpoints should be avoided, as well as on other scopes different from the need to disseminate the results of research, such as the institutional approach (public vs. private); the content-related approach (basic vs. applied); the yield-related approach (on the base of the gain arising from research activities).

On the other hand, all tools for the implementation of human rights could be put in place, including the *Drittwirkung* theory, according to which national courts can implement fundamental rights of international origin in relations between individuals(60).

In any case, new legislative measures should be proposed to regulate the phenomenon considering the general interest and the other ones, as far as human genetic information is concerned; or it would be important to establish mechanisms of global governance in relation to access to genetic resources, and not only let the State regulating a so essential subject for the entire planet and for humanity as a whole(61).

7. — *Civil enforcement of rights concerning genetic information.*

If the best legal framework to protect the rights arising from genetic information are the human rights and not the «proprietary paradigm», this does not mean that the instruments provided by Civil Law are not useful also in these matters.

Firstly, the Contract Law provides the basic instruments to regulate the use of genetic information, through the «consent».

The consent is provided for the health treatment by national Constitutions(62), as well as by the supranational legal sources such as the

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(60) See D. SPIELMAN, *L'effet potentiel de la Convention européenne des droits de l'homme entre personnes privèes*, Luxembourg, 1995.

(61) S. OBERTHÜR, G.K. ROSENDAL (edited by), *Global Governance of Genetic Resources*, Nueva York and London, 2014.

(62) Swiss Constitution, Article 118b, entered into force on 2010, disciplines informed consent in the research on humans. Also the Constitutions of Bulgaria of 1991 (Article 29),

EU Charter (see Article 3) or the additional Protocols of the Convention, especially the Protocol concerning genetic testing for health purposes (Strasbourg, 27 November 2008).

The consent to the use of genetic information of the persons is also provided by subconstitutional legal texts such as the French Civil Code, which requires the consent of the persons for all treatments (Article 16-3, paragraph 2 Civil Code), collecting their genetic information (Articles 16-10, 16-11, 16-12 Civil Code).

As above mentioned, the consent is also required by other legal text concerning privacy protection, as provided by the Article 8 par. 2 EU Charter, and the Directive 95/46/ EC and the Regulation (EU) 2016/679.

According to the definition contained within the Article 2 of the above mentioned Declaration of UNESCO, the consent is «Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored». On the other hand, Article 7 of the Directive on the protection of personal data sets out that the consent consists in «any freely given specific and informed indication of his wishes» (Article 2.h).

It is quite clear that the consent shares with the contract and other kinds of agreements the element of expression of will aiming to achieve finalities recognised by the law.

Furthermore, the consent and other kinds of agreements are considered as legal instruments to implement the system to access and to share genetic resources (*Mutually Agreed Terms*, *Prior Informed Consent*, *Material Transfer Agreement*), as set out by the Convention on Biological Diversity (in particular, see Article 15), and by other legal texts above mentioned, such as the Nagoya Protocol, the ITPGRFA, the Regulation (EU) no. 514/2014.

In both above mentioned cases, even if the will of the holder of the rights to protect cannot be considered absolute, because the other interests should be considered too, however the contractual instruments may be a

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Slovenia (Article 18), Hungary (Article III, par. 2) and Croatia (Article 23) prohibit medical or scientific experimentation without the consent of the person concerned.

good opportunity to realise an equilibrium: between the interests of genetic material suppliers (mainly developing countries) and the interests of users (usually multinationals or subjects of industrialized countries); between the interests of the persons holding genetic information, and those of her/his genetic family or of the research.

Secondly, in the matters considered within the present paper, it is possible to implement the rules of the civil liability to restore the violation of the fundamental interests by States or individuals which affect rights concerning genetic information, or in case of arbitrary use of those rights.

The affirmation of the civil liability of the States is the result of a process of external and internal limitations of the concept of sovereignty.

In case of no fulfilment (positive or negative) of obligations provided by EU law, for example, the Court of Justice recognises the liability of the State, whatever the organ of the State whose action or inaction has caused the failure(63), even when they are constitutionally independent(64), such as a local authority or the judicial power.

Also the European Court of Human Rights, in its case-law about the State liability, implements Articles 41 and following of the ECHR, providing that « If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party». The compensation is decided in order to enforce the respect of the human rights, even if they are not connected to the patrimonial sphere(65).

Furthermore, the Court of Strasbourg often makes reference to the

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(63) Among the other cases, see for example ECJ, 11 December 1990, C-34/89, *Italy/Commission*, ECR 1990, I-3613, which makes reference to the lack of adoption of the acts in order to remedy to the irregularities of the beneficiaries of the EU grants.

(64) ECJ, 9 December 2003, C-129/2000, *Commission/Italy*, ECR 2003, p. I-14672.

(65) Just as an example, among the last judgements, see the judgement of EctHR in the case *Mennesson v. France*, application no. 65192/11, of the 26 Jun 2014, concerning the violation of the right to respect of family life (Article 8 ECHR), in case of the lack of recognition of the filiation arising from the surrogacy forbidden by the domestic legislation (in the case the French law).

protection of the patrimonial rights, especially the property recognised by the Article 1 of the Additional Protocol to the Convention, also when it wishes to grant the protection of personal rights.

It is the case of the case-law Maurice and Daon of 2005, where the European Court decided that the French law no. 2002-203 (also known as «*loi anti-Perruche*»), which has limited the medical liability in the event a malformation of the foetus, also for the controversies raised before the law entered into force, did not comply with the duty to respect the credit as a form of property.

If, as stated above, the human rights impact on the discipline of contracts and the latter may grant a protection of those rights, this situation leads to a series of new legal problems.

The legal disciplines of the contract and of the civil liability arises from a patrimonial perspective, as provided by the Civil Codes and by the tradition of the Civil Law.

Surely, some traditional rules concerning contracts and obligations appear as not consistent with the scope to protect the personal rights.

This is the case of contractual capacity and the right to withdraw.

With respect to the first question, according to the Civil Codes, only the persons above a specified age (usually 18 years) and who not have been declared incapable by the judicial authority because of severe mental disabilities or as a consequence of penal sanctions may act as parties of contracts.

The International Ethical Guidelines for Biomedical Research Involving Human Subjects of 2002, the Council for International Organizations of Medical Sciences, according to which «those who are relatively (or absolutely) incapable of protecting their own interests», seem to refer to the incapability.

However, in the case of non-patrimonial interests those rules, if applied strictly, would lead to the violation of constitutional principles of great relevance(66).

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(66) In fact, Article 12 of the UN Convention on the Rights of Persons with Disabilities establishes different rules. First, that provision states that « persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life. » (see paragraph 2). This also in case of personal issues as those relating to informed consent.

In this context, European sources prefer, to a formal definition of capacity, an objective approach based on two substantial and dynamic notions, such as the «competence»(67) to receive relevant information and to give consent. In fact competence can be defined as the attitude «to understand relevant information, to evaluate that information and make a reasoned decision, to decide without undue influence, and to communicate consent or refusal»(68).

Therefore, according to the definition of competence, the traditional notions of capacity is not applicable.

Furthermore, the agreements used to protect fundamental rights may derogate other traditional principles such as the rule of immutability of the dispositions set out by the parties of the contracts. It is the principle of *pacta sunt servanda* which is affirmed at international and national level (see the Article 1372 of Italian Civil Code stating that the contracts «have the force of the law between the parties»).

In case the agreements are used to protect personal rights, that principle cannot be accepted(69).

The consent to a therapeutic or other intervention on the personal sphere of the individual may be allowed until when the person concerned agrees. Indeed, the consent may at any time be freely withdrawn (see Article 5 Convention of Oviedo; see also Article 13, par. 3, Additional Protocol of

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(67) There is not an agreement on the notion of «competence». Among other see T.L. Beauchamp, J.F. Childress, *Principles of Biomedical Ethics*, Oxford, 2009; A.E. Buchanan, D.W. Brock, *Deciding for Others: the ethics of surrogate decision making*, Cambridge, 1990; C.M. Culver, B. Gert, *The inadequacy of incompetence*, in *Milbank Quarterly*, 1990, 68: pp. 619-643; J.F. Drane, *The many faces of competency*, in *Hastings Centre Report* 15, 1985, no. 2, pp. 17-21; M.F. Jonas, *Competence to consent*, in R.E. Ashcroft, A. Dawson, H. Draper, J.R. McMillan (coord.), *Principles of Health Care Ethics*, Chichester, 2007, pp. 255-262.

(68) European Commission, *European Textbook on Ethics in Research*, Brussels, 2010, p. 55.

(69) According to the differences between contracts and content, see P. Perlingieri, *Il diritto alla salute quale diritto della persona*lità, in *Rass. dir. civ.*, 1982, p. 1020 ff., today in Id., *La persona e i suoi diritti. Problemi del diritto civile*, Napoli, 2005, p. 101 ff., esp. p. 127; C. Castronovo, *Autodeterminazione e diritto privato*, in *Eur. dir. priv.*, 2010, p. 1037 ff., p. 1053; A. Sassi, *Testamento biologico e protezione del malato nella società della conoscenza*, in R. Cippitani (ed.), *Società della Conoscenza e Cultura dell'Integrazione*, Roma-Perugia-México, 2012, p. 349 ff., esp. p. 369.

biomedical research; Article 9, par. 2, od Additional Protocol to the Oviedo Convention on genetic testing for health purposes, 2008).

Anyway, the above-mentioned adaptions of the Civil Law instruments (and the others), do not exclude the application of many rules concerning the contracts or the civil liability.

Furthermore, it possible to observe a progressive convergence between patrimonial and personal rights (70), in order to better protect the fundamental rights (71).

Therefore, the Civil law provides the legal instruments to reach, in an efficient, flexible and pervasive manner, the aims recognised by the legal system, including the protection of the fundamental rights. This one is not only let to the political decision of the States, but they become enforceable before any kind of judge in all controversies.

This function of private law, and especially of contract law, is not so surprising.

Private law shows great vitality in adapting itself to new and unexpected demands of society and the economy (72).

Anyway, today private law demonstrates its strength and versatility, rediscovering its ancient and modern main function, which is to provide the legal-logical tools (such as contract) to solve problems in the relations between individuals, whatever the subjects involved might be (private and public entity or States).

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(70) See, for example, G. Resta, *Autonomia privata e diritti della personalità*, Napoli, 2005, p. 13 ff.; D. Lefranc, *L'auteur et la personne (libres propos sur les rapports entre le droit d'auteur et les droits de la personnalité)*, in *Recueil Dalloz*, 2002, 1926 ; T. Hassler, *La crise d'identité des droits de la personnalité*, in *Les Petites Affiches*, no 244, 7 dec. 2004, pp. 3-11; M. Bui-Leturcq, *Patrimonialité, droits de la personnalité et protection de la personne, une association cohérente*, in *Revue de la Recherche Juridique*, 2006, p. 767; E.H. Reiter, *Personality and Patrimony: Comparative Perspectives on the Right to One's Image*, in *Tulan Law Review*, 76, 2002, pp. 673-675.

(71) R. Cippitani, *The «Contractual Enforcement» of Human Rights in Europe*, in A. Diver, J. Miller (edit by), *Justiciability of Human Rights Law in Domestic Jurisdictions*, Cham (ZG), Springer, 2016, pp. 308-331.

(72) M. Pennasilico, *L'interpretazione dei contratti della pubblica amministrazione tra conservazione e stabilità degli effetti*, in *Rass. dir. civ.*, 2005, p. 432 ff.