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CHAPTER 55

BIOETHICS AND BASIC RIGHTS: PERSONS, HUMANS, AND BOUNDARIES OF LIFE

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The basic concept of human rights is that people have certain moral rights by virtue of being human. But it does not follow from this concept that international instruments of human rights and the national constitutions protect all rights agreed or shared within international or national communities. The recent incorporation of certain bioethical norms into constitutional amendments and, more typically, into new interpretations of general constitutional rights in the domain of health care, therefore, is a result of a long history. Moreover, bioethics and human rights have, for many decades, developed separately. The two disciplines have different historical roots; they each have distinct scopes, perspectives, and methods of interpretation. Except for the right to be informed before a 'medical experimentation', which appeared

soon after the Second World War,[1] many of the bioethical norms have been formulated as basic human rights only in the last decades of the twentieth century. Furthermore, it should be emphasized that rights and values within bioethics are not regarded as automatically transferable to constitutional rights, nor even to statutory rights.

The main point of departure from the previous, paternalistic model[2] was the possibility to treat many chronic diseases, and the availability of several non-therapeutic interventions, biomedical research, genetic screening, and reproductive services. These medical interventions presuppose entirely different doctor–patient relationships than, for instance, in emergency care. The patients' autonomy, their views on life, are material in the decisions on making choices between different alternatives. Furthermore, by the beginning of the twenty-first century, several new technologies, such as genetic testing, assisted reproduction, stem cell research and therapy, nanotechnology, synthetic biology, and neuroscience have provided insights into basic processes of life, human behavior, and human heredity. The splendid isolation of science has been seriously questioned by social scientists, bioethicists, and by the public; science is no longer regarded as a value-free pure domain of research. Its ambition to unlock the basic elements of our human existence required a common thinking on the implications.

In this chapter, the connections between bioethics and basic rights will be explored partly by analyzing the basic legal norms of bioethics, and partly by comparing thematic cases from the jurisdictions of the European Court of Human Rights (ECtHR) and the US Supreme Court, as well as some cases from other jurisdictions. I will primarily focus on two major lines of thought in contemporary bioethics: the first is concerned with the boundaries of life (eg issues of embryo research, assisted reproduction, and end of life decisions) and the second is related to the contemporary exploration of the frontiers of the human body (issues such as the use of human tissues and human DNA for research and other purposes). In what follows, I will examine questions that are eminently bioethical but I will not tackle problems that arise in the context of general moral concerns, such as the permissibility of abortion—which will only be considered when *sui generis* bioethical issues, such as access to prenatal genetic tests or the institutionalization of informed consent before the termination of pregnancy or sterilization, emerge at the intersection of basic rights and bioethics.

I. Bioethics and Human Rights

Bioethics traditionally focuses on establishing moral limits between different types of acts in the field of life sciences and their medical application. There is no established method to recognize the moment when some universal norms have crystallized from the literature of bioethics and when they become basic rights in fields of bioethics.

Since its first use, the term 'bioethics' has had at least two different meanings, one broader than the other. The broader concept was coined by Van Rensselaer Potter in 1970[3]

[1] In 1949, the Nuremberg Code adopted the rules of medical experimentation as a response the basic violations of human rights during the Second World War; the International Covenant on Civil and Political Rights, 1966. Art 7 states that 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.'

[2] Exceptionally, some early judicial decisions had already recognized the doctrine of consent, such as the famous decision of Cardozo in *Schloendord v Society of New York Hospital* 211 NY 125, 105 NE (1914).

[3] He first used the term in a 1970 article and then in his book: Van Rensselaer Potter, *Bioethics: A Bridge to the Future* (1971).

and it advocates a comprehensive and global view of bioethics that integrates even environmental ethics. A different type of interpretation was advocated by André E. Hellegers[4] who used the term 'bioethics' for the first time in an academic field of learning and in the context of public policy and the human life sciences. Bioethics in this view is a way of approaching and resolving moral conflicts generated by a new concept of medicine. This more restricted view has become dominant in much of the theory and practice of bioethics.

Recently, bioethics has also been regarded as a discipline that provides a critical perspective not only on the practice of medicine and biotechnology, but also on the traditional framework of human rights. Therefore, authors such as Brooke A. Ackerly consider grouping bioethics together with queer theory, cultural studies, critical race theory, and multiculturalism as a critical approach to the universal human rights.[5] Indeed, bioethics shapes the contours of basic rights in two different ways. First, it broadens the catalog of basic rights or at least aims to stretch the interpretation of rights to the domain of bioethics. Secondly, the bioethics movement extends to the subjects of protection, for example to 'future generations'. In other words, bioethics encompasses not just biological but also legal and philosophical conceptions of the person.

1. The Influence of Normative Bioethics

Human rights instruments after the Second World War paid little attention to issues related today to bioethics except for the problem of 'medical experimentation without consent'. The turn occurred around 1997 when the Human Genome Project[6] and the possibility of cloning mammals put bioethics at the forefront of human rights debates. And even though all attempts at human cloning have failed thus far, it is still considered to be one of the most controversial problems in bioethics, both from political and legal perspectives. This fear even motivated the United Nations to draft an international declaration specifically on human cloning which prohibits all forms of cloning if they contradict the protection of human dignity.[7]

The fundamental principles of bioethics are recognized in international declarations developed under the aegis of the UN network. The General Conference of UNESCO has adopted three significant, though not binding, international declarations.[8] The first, and most important, is the 1997 Universal Declaration on the Human Genome and Human Rights, and the title itself is a telling reference to the Universal Declaration of Human Rights (UDHR). This declaration has led to the development of universally accepted bioethical principles, such as respect for human dignity, non-commercialization, benefit sharing, and scientific progress, which have attained high recognition in international law, at a level equivalent to that of the UDHR. This Declaration repeatedly evokes the concept of 'human dignity': in referring in Article 2 to

[4] Warren Thomas Reich, 'The "Wider View": André Hellegers's Passionate, Integrating Intellect and the Creation of Bioethics' (1999) 9 *Kennedy Institute of Ethics Journal* 25–51.

[5] Brooke A. Ackerly, *Universal Human Rights in a World of Difference* (2008), 57.

[6] In various societies, and also in science, several different kinds of meanings and uses can be attached to human genes. Genes can be conceived as sources and information for research, for forensic identification, tools for therapy, information for actuarial calculus, and for many other uses.

[7] The 59th General Assembly adopted the United Nations Declaration on Human Cloning on March 8, 2005 by a vote of 84:34:37.

[8] The chronologically second to be adopted International Declaration on Human Genetic Data, which will not be discussed here, laid out norms for conducting research on human tissues and DNA and has served as a model for several laws on the protection of human DNA.

the uniqueness of the human genome and in Article 11 as a reason for prohibiting reproductive cloning.[9]

Additionally, Beauchamp and Childress have developed four major principles of bioethics[10] which have since been used worldwide in analyzing cases, as well as in ethics education. These four principles are: *respect for autonomy*, which means respecting the decision-making capacities of autonomous persons that enable individuals to make informed choices; *beneficence*, which considers the balancing of benefits of treatment against the risks and costs; *non-maleficence*, which dictates avoiding harm; and finally *justice*, which is applicable in deciding both the allocation and costs, and the benefits and risks within health-care systems.

2. Is There a Common European Approach?

The recognition of the above principles and the emergence of the constitutional and human rights aspects in bioethics are reflected at the regional supranational level. The Charter of Fundamental Rights of the European Union, now legally binding within the scope of EU law, offers a catalog of common bioethical principles, such as human dignity and integrity and the right to life. Regarding human integrity, the Charter refers to free and informed consent, non-commercialization, and the prohibition of eugenic practices and human reproductive cloning. Human embryonic research and the boundaries of human embryonic stem cell (hESC) research, issues central to the European debate, are not addressed directly.

Bioethics and ethical aspects of new technologies are viewed within the European Union as subjects that fall within the competence of the member states, as part of EU commitments to ethical pluralism and the principle of subsidiary. Nevertheless, over the years an increasing number of European norms have been adopted that are to be considered with regard to biomedical research. One part of these norms contains safety requirements, but an increasing number of legal requirements that are similar to ethical standards have been formulated.

A further interesting feature of the European approach is that—even though several international ethical norms, such as the Helsinki Declaration, are not legally binding—for international research projects to be financed by the Commission, they must comply with a number of ethical norms that are otherwise not included in legally binding European norms. In general, though, the European framework indicates that diversity among European states is the prevailing characteristic of regulating the ethical boundaries of biomedical research.

3. The European Convention of Human Rights and Biomedicine

Though the European Convention on Human Rights (ECHR) was adopted in 1950, bioethics was not included in it until the 1997 Oviedo Convention of the Council of Europe. However, the lack of universal endorsement indicates the ongoing constitutional differences and differences in national interests among the European states.[11] The European nature of the document

[9] The latest of the three, the 2005 Universal Declaration on Bioethics and Human Rights, deals with this subject more generally, as a further indication that bioethical norms have attained high recognition in international law.

[10] Tom L. Beauchamp and James F. Childress, *Principles Biomedical Ethics Oxford* (6th edn, 2008).

[11] eg Germany has not signed the Oviedo Convention because of the ambiguity on certain terms, such as 'health purposes' and 'genetic counseling in case of predictive genetic test' (in Art 12). Jürgen Robienski and Jürgen Simon, 'Recent Development in the Legal Discourse on Genetic Testing in Germany' in Andre den Exter (ed), *Human Rights and Biomedicine* (2010). The Oviedo Convention is a living instrument in the sense that it provides a gradually expanding field for biomedical law and bioethics, due to the (exercised) ability to amend it with additional protocols.

is expressed by the emphasis laid on human dignity as the fundamental value in biomedicine. Its scope is both broad and ambiguous: instead of the term 'everyone', 'all human beings' is used, which indicates a more biologically oriented notion of legal subjects[12] as well as the ambition to cover a broader field of subject.[13]

4. Bioethics and the European Convention on Human Rights

While the legal regulation of bioethics is principally covered by the national systems of the member states, the jurisprudence of the ECtHR reveals the contradictions and dilemmas of the prevailing European constitutional approach. The ECtHR follows the logic and limits of the ECHR, but within the frame of the rights protected under the Convention the ECtHR has had to reflect on bioethical dilemmas. It follows from the 'living instrument' approach that the ECHR reflects on moral or/and technical progress in various fields. However, general moral concerns and bioethical concerns should be differentiated. For instance, general religious and other moral concerns often appear in the legal debates on the permissibility of abortion.[14] However, when the content of informed consent before abortion or the accessibility of less invasive methods of abortion, or access to prenatal genetic tests appear before the Court, then rules and principles of bioethics can be taken into consideration, such as the principles of autonomy or non-maleficence.

5. Bioethical Considerations in National Constitutions

Recent advances in biomedicine and biomedical research have raised ethical concerns that have forced international and supranational organizations to take a stand and incorporate bioethical norms into various conventions, declarations, and recommendations. On the national level, however, this process has resulted mainly in specific statutory provisions in health-care law, civil law, family law, and data protection law. In other words, constitutions, with some minor exceptions, have remained untouched by this normative process.[15]

Despite the overall lack of specific constitutional provisions on bioethical issues, the application of the concepts of dignity, liberty, privacy, freedom of expression, and freedom of scientific research can offer some help in interpreting and analyzing the legal contours of contested new technologies. But as Sheila Jasanoff has stated, the 'Constitution provides no guidance on the questions of how social change in general, and scientific change particular, should bear on the interpretation of constitutional prohibitions or guarantees.'[16]

Human dignity plays a central role in basic rights and values in several constitutions, and also in the basic international norms of bioethics: for instance, in the Oviedo Convention[17]

[12] Article 1; similar concerns are raised by Umberto Vincenti, *Diritto senza identitá: La crisi delle categorie giuridiche tradizionali* (2007).

[13] One of the most debated parts of this Convention among the member states is Art 18 on research on embryos *in vitro*, which will be discussed later.

[14] On the constitutionalization of abortion, see Chapter 51.

[15] Among the exception provisions of recently adopted constitutions or constitutions of new states are, eg, Art 17 of the Constitution of the Slovak Republic which declares 'the law will specify in which cases a person can be admitted to, or kept in, institutional health care without his or her consent.'

[16] Sheila Jasanoff, 'Biology and the Bill of Rights: Can Science Reframe the Constitution?' (1987–88) 13 *American Journal of Law and Medicine* 249–89.

[17] Oviedo Convention (emphasis added):

> Article 1—Parties to this Convention shall protect the *dignity* and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

and in the Universal Declaration of Bioethics and Human Rights. Dignity can serve as a basis for several rights such as self-determination, right to refuse medical treatment, and equal respect; all relevant in the field of treating vulnerable patients. (See Chapter 18.)

A further fundamental constitutional pillar is the freedom of science. This is expressed in numerous constitutions (see eg Art 5 of the German Basic Law; Art 33 of the Italian Constitution; Art 59 of the Slovenian Constitution).[18] Protecting the freedom of science has been interpreted as safeguarding scientific research and the dissemination of research results from undue influence, such as censorship or state control for the purposes of using science as a biopolitical goal. However, commercial interests may distort scientific results and their application, and this is also an emerging challenge for constitutionality.

The constitutional principle of scientific freedom, however, does not presuppose that science is a value-free and objective enterprise. Judicial interpretation runs into difficulty when it has to analyze scientific activity in a complex way: to separate scientific advances from commercial interests, to peel off the legacy of an older, paternalistic professional tradition, and to deflect eugenic and reductionist thinking.

In the constitutions that do offer explicit provisions relevant for bioethical questions—similarly to international conventions and declarations—the most recent issues (even theoretical possibilities, such as reproductive human cloning) have attracted more attention than the classical issues (such as informed consent, death, and dying).

Article 24 of the Serbian Constitution[19] declares that 'Human life is inviolable. There shall be no death penalty in the Republic of Serbia. Cloning of human beings shall be prohibited.' It is interesting to note that while international bioethical norms prohibit human cloning based on the principle that it violates human dignity, the Serbian approach derives this prohibition from the right to life. One can assume that while the dignity-based approach focuses on the moral aspects of cloning human beings, the right-to-life-based prohibition places the emphasis on safety, as human cloning (in its currently developing state) threatens life.

One of the most detailed constitutional frameworks of bioethics is provided by the Swiss Constitution, which details conditions for research conducted in the fields of assisted reproduction and gene technology. Donation of the human embryo and human ova are prohibited and even the number of harvested human oocytes is maximized in the Constitution. Organ and oocyte trade, as well as surrogacy, are also *expressis verbis* forbidden in the Swiss Constitution.

The rich constitutional dimension of bioethics can be further demonstrated by the lively debate on anonymity in assisted reproduction. As a result of public debate initiated by a referendum, the Swiss Constitution has recognized the right to genetic identity.[20]

In the US context, a unique example is the California Stem Cell Research and Cures Act that resulted in adding Article XXXV on Medical Research to the California Constitution. Section 5 of this article establishes a constitutional right to conduct stem cell research. Section 3, however, prohibits funding for reproductive cloning.

Peru, Paraguay, and Chile express in their constitutions a strong pro-life position, where a major issue is even whether the use of contraception contradicts the right to life as enshrined in the Peruvian Constitution.

[18] Freedom of science, although it may seem to support a liberal position for a new technology, does not however help to predict legal attitude. Eg both Italy and Germany adopted a conservative law on assisted reproduction.

[19] The Serbian Constitution was adopted in 2006.

[20] Dominique Manaï, 'La procréation médicalement assistée en droit suisse: Verité sur la conception et l'identité du donneur de gamètes' in Brigitte Feuillet-Liger (ed), *Procréation médicalement assistée et anononymat* (2008), 264–5.

The Inter-American Commission on Human Rights held that the Costa Rican Constitutional Court decision prohibiting *in vitro* fertilization (IVF)[21] itself violated the right to be free from arbitrary interference with one's private life, the right to found a family, and women's right to equality.[22]

II. The Jurisprudence of Core Bioethical Questions

1. Beginning of Life and Reproductive Rights in Light of New Technologies

The edges of life constitute the fields where most bioethics problems arise. Moral limits and legal frontiers of euthanasia and end of life decisions, as well as termination of pregnancy, have resulted in many constitutional and human rights cases. In cases of assisted reproduction, with the advent of new technology courts have had to face numerous bio-cultural issues and differences that they had never faced in the context of non-medicalized reproduction.[23] In the domain of reproductive rights, the right to privacy (in the United States) and the right to private and family life (in Europe) provide the main pillars of the constitutional framework.

One of the most rapidly developing fields is the interpretation of procreative liberties vis-à-vis new reproductive technologies. At the European level, there is no consensus on the nature and status of the embryo and/or fetus, although they are beginning to receive some protection in light of scientific progress and the potential consequences of research into genetic engineering, medically assisted procreation, and embryo experimentation. The ECtHR is convinced that it is neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the unborn child is a person for the purposes of the right to life provision in the Convention (*Vo v France*).[24]

Recent cases concern access to IVF, wrongful life and birth, and custodial rights over embryos. In these instances, the potentiality of life has to be assessed but the applicability of abortion case law is disputable. For instance, the very same legal regimes that allow termination of pregnancy during the first trimester based on the request of the pregnant woman may come to an entirely different conclusion when a woman expresses her wish alone to have an *in vitro* embryo implanted in her.

The complexity of the legal questions of assisted procreation has urged many countries to establish a specialized board of ethics with the aim of mapping both the ethical and legal issues before legislation, incorporating ethical concerns into recommendation for legislation.[25] Perhaps it is this focus on ethics that has led to the very different legal solutions even within

[21] No 2306 of 2000.

[22] Report No 85/10, Case 12.361.

[23] On the related conceptual uncertainties see Marcia C. Inhorn (ed), *Reproductive Disruptions* (2007).

[24] *Vo v France*, App no 53924/00, 8 July 2004. See further *Brueggemann and Scheuten v Germany* (1981) 3 EHRR 244; *Paton v United Kingdom* (1981) 3 EHRR 408; *Open Door Counselling v Ireland* (1993) 15 EHRR 244; *Evans v United Kingdom*, App no 6339/05, 10 April 2007, nyr; *SH and Others v Austria*, App no 57813/00, 1 April 2010.

[25] See eg Warnock Committee in the United Kingdom (1982); Benda Commission (1984) in Germany. The report submitted by Noëlle Lenoir, entitled 'Aux Frontières de la vie: Pour une éthique biomedicale à la française', provided the foundation and adoption of French bioethics law in 1994. This '*ethics committee*' method was subsequently followed in the elaboration of several statutory laws, including the German law on stem cells.

Europe. For example, the United Kingdom and Spain have developed a liberal approach, while Germany, despite its strong embryo protection law, has allowed the import and use of already existing embryonic stem cell lines.

Assisted reproduction was one of the first widespread technologies that raised both ethical and legal questions. The ECtHR was faced with these questions in the *Evans v United Kingdom* case,[26] where the applicant claimed that her privacy rights were infringed by granting a legal possibility to destroy her embryos based on her partner's request. While access to many forms of IVF is accepted as a rule,[27] the issue here was the conflict between the rights of the prospective mother and the male producer of the embryo. It is the *in vitro* procedure and *ex utero* storage that create disruption between the phases of human reproduction. The legal contradiction here is that while assisted reproduction was developed with the aim of helping to ensure rights of the infertile and to grant them privacy and a health service that would eliminate the pain of being childless, the disruption of the procedure then created an opportunity to invade the privacy and right to family life in regular cases of reproduction. As the *Evans* case shows, procreative liberties are often recognized as negative liberties (women should not be prevented from carrying on their pregnancy), but this liberty is not applicable in cases of *in vitro* treatment when the Court recognized that here the father's right not to become a parent should prevail over the woman's interest in becoming a mother.[28]

This case may have many different interpretations. The Court took into account the assessment of the new reproductive technologies when it recognized the disruption of procreation and pregnancy in the case of *in vitro* treatment. However, the ethical theory it used is not clear, thereby showing that the logic of bioethics is not directly transferable into law which relies on traditional forms of rights and interests. If, in this instance, bioethics was of any influence then it was manifested only in reference to the main sources of bioethics.[29] A competing view, that would follow from bioethics, would take into account and assess the difference in the burden of physical involvement in the procedure. Lengthy hormonal treatment and invasive extraction of the human eggs pose significantly more of a burden on women than is the case with sperm donation.

The main ethical dilemma of the *Evans* case, therefore, was whether biological differences in gamete donation could be taken into account in assessing the rights of male and female donors. Furthermore, the Court missed the opportunity to recognize the difference between preventing someone from becoming a parent and the denial of the right to change opinion on biological parenthood.[30]

[26] *Evans v United Kingdom* (n 24).

[27] In *Dickson v United Kingdom* the ECtHR had to examine Art 8 and the refusal of facilities for artificial insemination to the applicants, a prisoner and his wife. The Court found that Art 8 was applicable as the article encompasses respect for the individual's decision to become genetic parents. In the case of *SH and Others v Austria* (n 24) on the prohibition of ova donation for *in vitro* fertilization adopted by the Austrian legislature, the Court took into consideration medical/scientific certainty as a condition for reproductive rights. Since IVF treatment gives rise to sensitive moral issues in the context of a fast-moving medical and scientific field, and since there is no common ground amongst the member states, the Court was of the view that a wide margin of appreciation should be afforded to member states.

[28] *Evans v UK* (n 24), para 71.

[29] In deciding, the Court provided a detailed comparison of the applicable legal solutions in the member states of the Council of Europe, referring to the Oviedo Convention, and to the principles set by the Steering Committee on Bioethics (CDBI) in 1989, and the 2005 UNESCO Declaration.

[30] On the other hand, Hungarian law permits the continuation of the procedure, by giving preference to the woman's wish, with information granted to the male. He may exclude the possibility of continuation for such cases, but may not decide so later when the treatment is already being performed.

2. Informed Consent Rules and Reproductive Rights

In the recent ECtHR case of *RR v Poland*,[31] the applicant was prevented from undergoing prenatal genetic testing within the statutory time limit within which abortion was still legal, despite her repeated requests to have access to a genetic test that could have confirmed whether her fetus was healthy. After several doctors in Poland refused to offer her the test, and when the genetic test was finally performed after significant delay, she had already missed the deadline for requesting an abortion. Eventually, the baby was born with Turner syndrome. According to the ECtHR, the right to access to this type of genetic information falls within 'the ambit of the notion of private life'.[32] In the absence of access to genetic test rights, protection would have remained 'theoretical or illusory'.[33]

3. Concept of Procreative Liberties and Bioethics in US Jurisprudence

US jurisprudence on procreative liberties developed parallel to the recognition of rights to privacy.[34] In addition, freedom of research in the United States in general has led to a favorable environment for various technologies in the field of assisted reproduction and procreative liberties.[35] It should be noted, however, that judicial views that support the concept of negative liberties in procreation do not automatically generate access rights to services to assisted procreation, at least in the US constitutional tradition. However, cases in the field of eugenic practices do often serve as a basis for critical reflections on genetics. Ever since the early eugenic episodes in science were reaffirmed by judicial acknowledgment, eugenic thinking and eugenic jurisprudence have served as a learning experience for the contemporary conception of how and what to regulate in science.[36]

Buck v Bell[37] is the seminal eugenic decision of the US Supreme Court, and is still one of the most frequently cited cases in the fields of disability, gender, and bioethics. The *Buck* Court upheld the constitutionality of non-voluntary sterilization in cases of preventing inherited 'degeneration', with Justice Holmes asserting that the 'principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes'.[38] The Supreme Court has never overruled the decision in the *Buck v Bell*, although society's perception of disability and on the value of life has entirely changed since the decision. In *Skinner v Oklahoma*,[39] the US Supreme Court, however, held unconstitutional an Oklahoma statute that provided for the involuntary sterilization of the poor and of certain categories of recidivists that were characterized by 'moral turpitude'. The Supreme Court determined that the Equal Protection Clause prohibited the enforcement of the Oklahoma statute which required sterilization of persons who had been convicted of certain specified crimes. The distinction between categories of crimes, nevertheless, indicated a hidden eugenic pattern of thought.

[31] ECtHR, *RR v Poland*, App no 27617/04, 26 May 2011.
[32] Ibid para 197.
[33] Ibid para 191.
[34] Elyse Whitney Grant, 'Assessing the Constitutionality of Reproductive Technologies Regulation: A Bioethical Approach' (2010) 61 *Hastings Law Journal* 997–1034.
[35] John A. Robertson, 'Procreative Liberty and Harm to Offspring in Assisted Reproduction' (2004) 30 *American Journal of Law and Medicine* 24–39.
[36] eg the Human Genome Project has been scrutinized since its inception by introducing Ethical, Legal and Social Implications (ELSI), a parallel project.
[37] *Buck v Bell* 274 US 200, 207 (1927).
[38] Ibid.
[39] *Skinner v Oklahoma* 316 US 535 (1942).

In *Griswold v Connecticut*,[40] the Court invalidated a statute that penalized the distribution of contraceptives. A further step was made in constructing reproductive rights in *Eisenstadt v Baird*,[41] when Justice Brennan held that 'if the right to privacy means anything, it is the right of the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decisions whether to bear or beget a child.'[42]

Roe v Wade[43] provided a trimester framework that guided states on whether they may regulate some elements of abortion. Furthermore, the *Roe v Wade* Court recognized the privacy rights of the pregnant woman and her attending physician in deciding about termination of pregnancy during the first trimester. Later, the *Casey* case[44] offered new possibilities for regulation provided that they do not pose an undue burden on women. However, although abortion cases are often cited in the context of new reproductive technologies, significant moral and practical differences between *in vivo* and *in vitro embryo* question or at least reduce the applicability of these norms. The possibility of *extra corporal* reproduction has resulted in numerous legal problems, such as postmortem reproduction, custodial rights over the embryo, right to identity, and medical confidentiality. In *Hecht v Superior Court*,[45] the Court did not find any public policy that would prohibit or deny postmortem insemination and, as a consequence, they granted access as the late partner had clearly expressed his wish before his death.

In the context of new reproductive technologies, access to IVF treatment seems to pose different kinds of legal problems in the United States than in Europe.[46] The validity of surrogacy agreements served as the basis of several Court decisions, such as the *Baby M* case.[47] In *Johnson v Calvert*,[48] the California Supreme Court rejected a claim by the gestational (surrogate) mother that she be recognized as the mother of the IVF child. Although birth may establish maternity, the Court developed a different standard by referring to genetic consanguinity and intention expressed by the genetic parents to raise the child. The recognition of family based on genetic ties rather than on marriage has also influenced paternity rights, which is demonstrated in numerous cases, such as the dissent in *Michael H v Gerald D*,[49] in which Justice Scalia in the majority opinion defended the marital/'unitary family' idea.

4. Research on Human Embryos and on Embryonic Stem Cells

One of the most sensitive issues in current bioethics is the research conducted on the (surplus, *in vitro*) human embryo. The Oviedo Convention[50] leaves the question of the status of the human embryo and research on the human embryo partially open by the provision of Article 18(1) which states that 'where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo'. Arguably, this could encompass the destruction of human embryos in an adequately safeguarded process for the purpose of hESC derivation. The more

[40] 381 US 479 (1965).
[41] 405 US 438 (1972).
[42] 405 US 438, 453 (1972).
[43] *Roe v Wade* 410 US 113 (1973).
[44] *Planned Parenthood of Southeastern Pennsylvania v Casey* 505 US 833 (1992).
[45] *Hecht v Superior Court* 20 Cal Rptr 2d 275, 287 (Ct App 1993).
[46] Richard F. Storrow, 'The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics' (2007) 28 *Cardozo Law Review* 2291.
[47] *In re Baby M* 109 NJ 396, 447–9, 537 A2d 1227, 1253–4 (1988).
[48] *Johnson v Calvert* 851 P2d 776 (Cal 1993).
[49] *Michael H v Gerald D* 491 US 110, 115 (1989).
[50] See n 11.

contentious provision in Article 18(2)—which has prevented ratification of the Convention by all Council of Europe states as it has been considered alternately either too liberal or too conservative—prohibits the creation of embryos for research purposes.

The Constitution of Ecuador in Article 49(1) explicitly prohibits research on human embryos. Germany and Switzerland prohibit all forms of human cloning whereas others, among them the United Kingdom, China, and Israel, allow the creation of cloned human embryos for research.[51]

A distinction should be made between cases where research on the human embryo is allowed for the purposes of improving reproductive technologies and cases where the embryo is harvested in order to produce embryonic stem cell lines.

When human biological materials are used as building blocks for stem cells, usually the act of harvesting biological materials poses other types of legal issues as it might involve an instrumentalization of the human body. In these new types of research, bodily substances are used in two different ways: they are used not only as sources and objects of scientific observation but also as materials for creating cell lines.

The influence of bioethics can also be seen in the latest development of the patentability of biotechnological inventions in the field of regenerative medicine. In order to provide the effective and harmonized legal protection of biotechnological inventions, the embryo needs to be given an autonomous definition in EU law.

The *WARF*[52] decision of the European Patent Office Enlarged Board of Appeal[53] confirmed in 2008 that the 'industrial or commercial use' clause, which was introduced to prohibit the commodification of the human embryo, excludes the patentability of hES cells or cell lines due to the fact that the production of hES cells requires the destruction of the human embryos used as their source. The decision did not, however, make a distinction between embryos according to their origin, developmental phase, and acceptable uses, a distinction key to national regulations on embryonic research. A landmark decision was made at the end of 2011 in the *Brüstle* case[54] when the European Court of Justice ruled that a process which involves the removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo, cannot be patented.

The need of the biotechnology industry for human embryos and their use for embryonic stem cell research and for therapy often results in incoherent legal solutions. In 2008, the Brazilian Supreme Court[55] upheld the Biosecurity Law that allowed the destruction of human embryos for the purposes of creating embryonic stem cell lines, while abortion has remained restricted in the country.[56] A double inconsistency can be observed in the German position on research on the human embryo: research on the human embryo is not authorized, although

[51] See <http://www.who.int/ethics/topics/cloning/en/>.

[52] Wisconsin Alumni Research Foundation is an entity at the University of Wisconsin which owned the rights of the invention.

[53] See <http://archive.epo.org/epo/pubs/oj009/05_09/05_3069.pdf>.

[54] C-34/10 *Oliver Brüstle v. Greenpeace eV*.

[55] Brazilian Biosecurity Law (11.105/2005), see <http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l20540518_text>.

[56] In the *Alyne da Silva Pimentel v Brazil* case, access to reproductive health care was confirmed by the UN Committee on the Elimination of Discrimination against Women (CEDAW). Governments have a human rights obligation to guarantee that all women in their countries have access to timely, non-discriminatory, and appropriate maternal health services. Even when governments outsource health services to private institutions, they remain directly responsible for their actions and have a duty to regulate and monitor said institutions.

the German Basic Law guarantees the freedom of research and science in broad terms; however, embryonic stem cell lines can be imported and used for research.[57]

In the United States, political ideological conflicts govern the issues of embryo research. The federal ethics committee created under the Clinton administration, the National Bioethics Advisory Commission (NBAC), in its 1999 report[58] accepted that ethical positions regarding the moral status of the human embryo differ in society and different sources of human embryos may attract different moral positions.[59]

The liberal ethical position on the federal level changed when in 2005 a report from the President's Council on Bioethics,[60] appointed by the Bush administration, suggested that in the United States the protection of human life from the earliest stages of development, including the human embryo, is an ethical norm widely accepted in society.[61] It held that seeking therapies by means of destroying human embryos is ethically unacceptable and in order to reconcile scientific progress with the requirements of bioethics, biomedicine must find ethically acceptable sources for hES cells. However, a state constitutional amendment granted a right to conduct stem cell research in California.

A 2007 Executive Order[62] gave priority to ethically responsible ways of conducting hESC research. It emphasized that ethically acceptable sources of hESC lines exclude cell lines which necessitate the creation of embryos for research purposes or destroying, discarding, or subjecting to harm a human embryo. It also held that the destruction of embryos violates the principle of non-commodification and that human embryos are 'members of the human species'. The Executive Order envisioned the United States progressing in biomedical research while maintaining the clearly established ethical boundaries and standards of medical research and respecting human life and dignity.

The debate reached another turning point in 2009 when the Obama administration reviewed the federal funding moratorium imposed in 2001. The 2009 Executive Order[63] emphasized the necessity of hESC research for the purposes of enhancing human biomedical knowledge and creating new therapies.

Biotechnological inventions enjoy broad protection in the US Constitution and jurisprudence. The US Constitution in Article I, section 8 authorizes the Congress 'to promote the Progress of Science and Useful Arts' by granting authors and inventors the exclusive rights to their works for a limited time. The breakthrough in the history of biotechnological patents

[57] Stammzellgesetz, Bundesgesetzblatt (Federal Law Gazette) June 29, 2002.

[58] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (1999), available at <http://bioethics.georgetown.edu/pcbe/reports/past_commissions/nbac_stemcell1.pdf>.

[59] In the encyclical letter *Humanae Vitae* (1968), Pope Paul VI condemned any form of direct interruption of pregnancy. Two exceptions were made: ectopic pregnancy and cancerous uterus. In these cases, death of the fetus was considered a secondary effect of removing the uterus in order to save the life of the woman.

[60] The President's Council on Bioethics, *Alternative Sources of Human Pluripotent Stem Cells. A White Paper* (2005).

[61] This view reflects mainly the official Roman Catholic position in which

> obtaining stem cells from embryos that remain after in vitro fertilization involves the intentional destruction of a genetically unique living member of the human species that deserves full protection from the beginning of its existence.... This judgement of the Church, however, is not directed against stem cell research as such, but is concerned only with the use of certain kind of sources for obtaining stem cells, and with the methods of collecting them.

Béla Somfai, 'Religious Traditions and Stem cell Research' in Judit Sándor (ed), *Society and Genetic Information: Codes and Laws in the Genetic Era* (2003), 88.

[62] Executive Order (13435 of 20 June 2007).

[63] Executive Order (13505 of March 2009).

occurred in the US case of *Diamond v Chakrabarty*,[64] which has since been labeled as granting patents on life.

In 2010, a preliminary injunction created uncertainty in the field of financing research on embryonic stem cells.[65] Since the Obama administration has developed a more favorable environment for embryonic stem cell research, the issue was whether the increasing number of new projects should consequently receive financial support. The main issue was whether the National Institutes of Health should fund additional research projects on stem cells that involve the destruction of the human embryo. One year later, the District Court ruled in favor of the National Institute of Health and removed this injunction.

5. End of Life Decisions in Europe

As methods of intensive therapies have significantly increased the possibilities for artificial prolongation of human life, several issues have been raised. Who should decide on the health care of the terminally ill? Who can substitute the decision of a patient in a persistent vegetative stage? The principle of *autonomy* can serve as an ethical basis in cases where the terminally ill are still capable of expressing their wish. However, the principle of *non-maleficence* would prevent doctors from complying with requests for refusal of medical treatment unless the law recognizes that this refusal is self-determination within the concept of human dignity or/and encompassed by the concept of interests of liberty. As suffering and death take many forms, diverse solutions have emerged to face this medico-legal problem in different cultures and legal systems. In such concrete cases, legal terms, such as 'euthanasia', have become confusing, because we tend to define it to include many different types of actions and inactions.

The simultaneous existence of individual autonomous action and the assistance of a physician or a relative usually lead to legal proceedings. As Derrick Beyleveld and Roger Brownsword point out, human dignity 'can encourage a paternalism that is incompatible with the spirit of self-determination that informs the mainstream of human rights thinking.'[66]

In all euthanasia debates, an accurate legal delineation between different forms of ending life is very difficult to achieve. Voluntary active euthanasia is legalized only in the Benelux countries while assisted suicide is not regarded as a crime in Switzerland. But what constitutes passive euthanasia is still debated in several jurisdictions.[67] The question is still dominated by two independently developed fields of law. While public health law focuses on the duties of physicians and requires professional integrity and the saving of life, the more recent legal developments based on patients' rights respect the right to self-determination even in cases where the patient refuses medical intervention.

Alternately, these decisions may be treated as outside the realms of the courts and may be left in the hands of physicians. The Dutch position was the first directly to target the issue of this confidentiality in end of life decisions and Dutch statutory law gradually developed based on the analysis of the publication of confidential decisions on ending life based on, and even without, the patient's request.[68] Less radical steps have been taken in other European countries,

[64] 447 US 303 (1980).

[65] *Sherley v Sebelius* 2010 US Dist LEXIS 86441.

[66] Deryck Beyleveld and Roger Brownsword, 'Human Dignity, Human Rights, and Human Genetics' (1998) 61 *Modern Law Review* 662.

[67] For more detailed analysis of the constitutional aspects of euthanasia see Violeta Beširević, *Euthanasia: Legal Principles and Policy Choices* (2006).

[68] Remmelink Report, September 10, 1991, the first, official government study of the practice of Dutch euthanasia.

and after a long debate the French Parliament recognized the right of the terminally ill to refuse medical treatment although it did not legalize active forms of euthanasia.

The most significant case on the legal dilemmas of assisted suicide appeared in *Pretty v United Kingdom*.[69] The applicant was suffering from a serious degenerative disease due to which she was paralyzed from the neck downwards. She requested the ECtHR to give her authorization for her to end her life in dignity and to guarantee her husband freedom from prosecution if he assisted her in committing suicide, an exemption that was denied in the United Kingdom. She claimed that the right to life also includes the right to self-determination in life-related issues. Consequently, life is a right and not an obligation. She submitted that this included the right to choose when and how to die, and that nothing could be more intimately connected to the manner in which a person conducted her life than the manner and timing of her death. The judges in Strasbourg concluded that the individual had no right to death, or life, in the sense that the legal system should accept the right to assist any suicide as a general principle. However, the Court acknowledged that

> under Article 8 that notions of the quality of life take on significance. In an era of growing medical sophistication combined with longer life expectancies, many people are concerned that they should not be forced to linger on in old age or in states of advanced physical or mental decrepitude which conflict with strongly held ideas of self and personal identity.[70]

The *Pretty* case generated significant debate on autonomy and terminal illness. Since then, several European countries, including Austria and Finland, have enacted laws on the recognition of continuing power of attorney which provide stronger guarantees of the self determination of the terminally ill.[71]

6. End of Life Cases in the United States and Other Jurisdictions

One of the main dilemmas in bioethics occurs when the principle of autonomy clashes with the principles of non-maleficence. In the language of constitutional law, similar hard cases appear when individual liberty and state interest in protecting life demand different solutions in cases of end of life decisions.

In the United States, there has been a piecemeal development of the recognition of liberty rights in the field of terminal illness. Thus, the lower court cases of *Karen Quinlan*,[72] *Bouvia*,[73] and *Re Conroy*,[74] and the Supreme Court *Cruzan*[75] case provided the main pillars of the recognition of some forms of euthanasia in cases of terminal illness or of persistent vegetative state. In *Cruzan*, although the US Supreme Court affirmed that the legal requirement of Missouri on *clear and convincing* evidence of the will of the patient who is no longer capable of expressing her wish does not violate the Constitution, it still provided a constitutional basis embedded in the liberty interest to encompass the wish to

[69] ECtHR, *Pretty v United Kingdom*, App no 2346/02, 29 April 2002.

[70] Ibid para 65.

[71] See further Recommendation CM/Rec(2009)11 adopted on 9 December 2009 at the 107th meeting of the Ministers's Deputies. The Recommendation promotes dignity and self-determination in the cases of terminal illness.

[72] *In the Matter of Karen Quinlan* 355 A2d 647 (NJ 1976).

[73] *Bouvia v Superior Court of the State of California* 2d 179 Ca App 3d 1127 (1986).

[74] 486 A2d 1209 (NJ 1985).

[75] *Cruzan v Director, Missouri Department of Health* 497 US 261 (1990).

terminate life-saving nutrition and hydration. However, this development towards extending liberty interests in end of life decisions was interrupted when the issue of whether medical assistance in suicide can be granted reached the Supreme Court in the *Washington v Glucksberg* case.[76]

In *Washington v Glucksberg*,[77] the US Supreme Court failed to recognize a fundamental right to access medically assisted suicide, based on the request of the dying patient. Instead, the Supreme Court held that Washington's prohibition against 'causing' or 'aiding' a suicide does not violate the Due Process Clause. The Court's reasoning was based on a historical argument, rather than acknowledgment of the conditions of liberty rights.

Different layers of statutory law may further shrink liberty interests: as exemplified by the issue in *Gonzales v Oregon*[78] in 2006, when the US Supreme Court ruled that State Attorneys General could not enforce the Federal Controlled Substances Act against physicians who prescribed drugs for assisted suicide in compliance with Oregon state law.

Outside the United States and Europe, a law legalizing euthanasia was adopted in the Northern Territory of Australia in 1995,[79] but was nullified by the federal parliament two years after it went into effect. In Canada, the *Rodriquez*[80] case tackled the issues of assisted suicide, requested by a patient suffering from a serious illness. The patient based her argument on the Canadian Charter of Rights and Freedoms, which provides in section 7 that 'everyone has the right to life, liberty and security of the person and the rights not to be deprived thereof except in accordance with the principles of fundamental justice.' Justice Sopinka, writing for a narrow majority, rejected the claim of the petitioner that she just wanted to determine the time and manner of her death, and therefore denied her request.

A very different logic was followed in the leading UK case, *Airedale NHS Trust v Bland*.[81] There, the House of Lords ruled in favor of those representing Tony Bland, a patient in a persistent vegetative state with no hope of recovery, allowing his artificial feeding, and therefore his life, to be ended. The court's decision was based on the reasoning that it was in the patient's 'best interests' for treatment to be withdrawn and that its discontinuance was in accordance with good medical practice.

7. Extending Basic Rights to Human Tissues and Cells

The legal concept of the right to privacy provides a theoretical foundation for guaranteeing various forms of self-determination over the human body. However, when the issue of disconnected body parts, human tissue,[82] and DNA is raised, the concept of privacy seems to be an insufficient legal category to describe the complex relationship between the donor and the stored human tissue samples that are used for research purposes. On the one hand, the human DNA sample symbolizes and represents the person but, on the other hand, it is also regarded as a gift or personal contribution to research of public interest, as a symbol of public participation. When we deal with the legal implications of genetic data or storing human tissue samples in biobanks, a preliminary legal question has to be addressed, namely whether we are facing a

[76] Ronald Dworkin, 'Assisted Suicide: the Philosopher's Brief', *New York Review of Books* (February 27, 1997).

[77] *Washington v Glucksberg* 117 S Ct 2258 (1997).

[78] 546 US 243 (2006).

[79] Rights of the Terminally Ill Act (1995).

[80] *Rodriguez* [1993] 3 SCR 519.

[81] *Airedale NHS Trust v Bland* [1993] 1 All ER 821.

[82] Christian Lenk, Judit Sándor, and Bert Gordijn (ed), *Biobanks and Tissue Research* (2011).

human rights problem or are we in a field which requires regulation of the safety and logistics of research on human DNA.[83]

Defining the boundaries of the human body is especially relevant and justifies legal scrutiny when we look at research conducted on human beings, because of the potential abuses and possibilities of psychological or physical harm.[84] However, most research carried out today is not conducted on human beings but on human tissue, blood samples, and human DNA. Humans as research subjects are not actually present in the laboratories when research 'on them' is carried out. In other words, more and more human research is done not on the human body but on human bodily substances.

Research rules therefore have to be developed in order to respond to these different kinds of uses. For instance, legally, it still matters how human biological materials are being collected, and consent for collection and for specific use should be a precondition for research. Legal policy should then differentiate whether the research material still carries personal information.

In the field of the application of genetic research, legal issues are mostly concentrated around the problem of how new genetic information affects our basic human relations, family ties, decisions over the reproduction, insurance, employment, and intellectual property. To be more precise, how genetic information should be qualified, what kinds of rights can be established based on this knowledge, who should hold this knowledge, and who is to control this intrinsically individual, wide-ranging information that can easily be obtained by others are all major legal issues. Is it the genetic sample itself that should be protected, or rather the data that can be revealed during an examination of the sample? Or is it both of them in an identical manner, the sample as a set of data or separately as human tissue, or that the DNA information should be regarded as a special type of personal data?

These concerns often manifest when considering *biobanks*,[85] where there are two main methods of considering related legal issues. One is the concept of privacy; the other is the question of ownership.[86] While privacy aims to restrict access to samples and data, current tendencies in interpreting ownership point towards increased demand for the public use of biobanks. A right to privacy in biobank regulations refers mainly to the protection of personal data in collecting, storing, and processing samples and data, as well as the techniques for

[83] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells; Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

[84] Judit Sándor, 'Body Immortal' in Jennifer Gunning and Søren Holm (eds), *Ethics, Law and Society III* (2007), 123–35.

[85] Human biobanks and genetic research databases (HBGRDs) are

> structured resources that can be used for the purpose of genetic research, which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information.
>
> Source: OECD Draft Guidelines for Human Biobanks and Genetic Research Databases, 2008.

[86] Judit Sándor, 'Legal Concepts of the Right to Privacy and Ownership in the Regulation of Biobanks' in Kris Dierickx and Pascal Borry (eds), *New Challenges for Biobanks: Ethics, Law and Governance* (2009), 123.

shielding data from the curious eyes of third parties. Most international norms and national laws focus on protecting the data subject while claiming enhanced guarantees for securing privacy and confidentiality in the domain of biobanks. Some authors, such as Graeme Laurie, have already elaborated a notion of *genetic privacy*.[87] Based on privacy concerns, the Dutch National Steering Committee decided in 2001 that samples in the national repository of dried blood spots of newborns have to be destroyed five years after the blood is taken.[88]

In the ECtHR, the most important ruling so far is *Marper v United Kingdom*,[89] which has had far-reaching repercussions: while it primarily dealt with human rights guarantees in criminal procedures in the context of storing DNA samples taken from criminal suspects, it also touched on the legal classification of genetic samples and data, ruling that 'the retention at issue constitutes disproportionate interference with the applicants' right to respect for private life and cannot be regarded as necessary in a democratic society'.[90] In the Court's view, all the unlawfully retained information—the fingerprints, the DNA profiles, and the sample itself—*qualify as personal data* under the data protection convention, since each one can be directly linked to the individual suspect.[91] *Obiter dicta* the Court also mentioned that both genetic samples and derived genetic data fall under the protection of private life,[92] which supports those who consider genetic material and data a special case because of the possibility of personal identification.

Moore v Regents of the University of California[93] is a US state case that deals with the use of human cells for research and for commercial purposes. While the Court ruled that individuals do not have an ownership interest in their cells after the cells have been removed from their bodies, it nevertheless recognized an important bioethical principle based on informed consent and on *fiduciary duties* by claiming that physicians need to disclose their research interests to their patients. Justice Mosk, in his dissenting opinion, was in favor of considering the patients' contribution to biological invention more significantly.

Not only individual patients but patients' groups may also actively participate in biomedical research. In 2003, in *Greenberg v Miami Children's Hospital Research Institute*,[94] a group of individuals provided samples and medical data for researchers to explore the Canavan disease. However, when a patent was developed, the patients were not notified and could not benefit from the new tests or its profits. The federal district court ruled that individuals do not own their tissue samples.

One of the most well-known debates over the ownership of biological samples was elaborated in *Washington University v Catalona*.[95] In this case, Dr William Catalona set up a biobank at Washington University and, over the course of 25 years, collected 3,500 samples from

[87] Graeme Laurie, *Genetic Privacy* (2002). Genetic data is seen as a special case as it is shared by relatives, and requires the re-interpretation of anonymity as even in the lack of personal identifier it may lead to a concrete natural person by a simple match.

[88] Jasper A. Bovenberg, *Property Rights in Blood, Genes and Data* (2006), 7.

[89] ECtHR, *S and Marper v United Kingdom*, App nos 30562/04 and 30566/04, 4 December 2008.

[90] Ibid.

[91] Judit Sándor, Petra Bárd et al, 'The Case of Biobank with the Law: Between a Legal and a Scientific Fiction' (2011) *Journal of Medical Ethics* (forthcoming).

[92] *S and Marper v United Kingdom* (n 89), 68.

[93] *Moore v Regents of the University of California* 51 Cal 3d 120 (Supreme Court of California 1990).

[94] *Greenberg v Miami Children's Hospital Research Institute* 264 F Supp 2d 1064 (SD Fla 2003).

[95] *Washington University v William J Catalona, MD* United States Discrict Court Eastern District of Missouri Eastern Division, No 4:03CV1065, E Dist Mo April 14, 2006, *William J Catalona, MD v Washington University*, 8th US Circuit Court of Appeal, Nos 06-2286 and 06-2301, (2007). In 2008, the US Supreme Court declined to review this biological specimen ownership case.

patients diagnosed with prostate cancer. In this case, agreements between the researcher and the donors were overridden by the fact that the biobank had been used by the university for public purposes. The Court regarded the biological sample collection differently from a biobank, and considered it as a public entity belonging to the university and not to the scientist. The Court held that individual donors who provide biological specimens for research do not 'retain an ownership interest allowing [them] to direct or authorize the transfer of such materials to a third party'.

These disputes have also reached the field of intellectual property law. In 2010, a US district court invalidated Myriad Genetics' BRCA gene patent claims,[96] finding that human intervention and isolation did not produce markedly different characteristics than those possessed by genes in the human body. A federal court of appeals further held that isolated DNA may be unpatentable, as in order to state that a product of nature is patentable it must be qualitatively different from the product occurring in nature with markedly different characteristics from characteristics found in nature. In July 2011, the Court of Appeals for the Federal Circuit[97] partially reversed the lower court's decision and held that 'isolated' DNA, including genes and sequence-specific probes for detecting breast and ovarian cancer, are patent-eligible subject matter, since these molecules are 'markedly different' new chemical entities that do not exist in nature. Even after this judicial compromise that gives some gesture to the biotechnological industry, the debate on the patentability of human genes has not been settled.

Cases on property and privacy rights in relation to human tissues and cells point to a general theoretical problem, namely what are the frontiers of individual self-determination in respect of human tissue samples. Is my DNA and tissue is still *me*? Even if it is not identical with the individual, would it increase or, on contrary, decrease the protection of the individual if the law is becoming more permeable at the frontiers of the self? Here it seems that the 'bioethical mission' has influenced the previous legal notions and a more complex bio-social concept of the human being has been extended protection.

III. Conclusions

The perspective of bioethics increasingly serves as a tool for framing and interpreting various emerging biomedical technologies and helps to assess their moral and legal implications. Bioethics as a discipline, however, is relatively new and therefore its theoretical positions, legal interpretations, and policy consequences are not yet well known among the judiciary or at least not sufficiently elaborated to be widely used in court cases. As a result, courts often limit their references to bioethics discourse to a mere listing of various binding and non-binding instruments, even disregarding their scope and context.

However, if one examines closely the discourse on the legal subjects of rights in biomedicine, a significant extension of the field can be observed. Respect for human dignity, and the right to privacy, is used to interpret the decisions on human biological materials, DNA samples, decisions over the custodial rights of the *in vitro* embryo, and is even applicable in shaping the right to decide what types of research are to be conducted on previously collected biological samples.

[96] *ACLU v Myriad Genetics* 09 Civ 4515.

[97] See <http://www.genomicslawreport.com/wp-content/uploads/2011/07/Decision-in-USPTO-vs-MYGN.pdf>.

Judiciaries worldwide are facing these complex issues of the developing bio-social identities of humans and, in this field, bioethics seems to do significant preparatory work by exploring fundamental ethical issues and implications of new biotechnologies. Not all of these concerns should be recognized as basic rights but bioethics serves as an important laboratory in crystallizing basic norms and methods for interpreting new technologies in the field of life sciences.

Law should avoid two extreme positions in respect of these new technologies. One is to avoid over and premature regulation, which happens when the law jumps too quickly to the latest scientific advances without leaving sufficient time for reflection on the ethical and social implications of a new technology. The other extreme position, which is more common and has its roots in several constitutional traditions, is the clear separation thesis in which judges refrain from touching 'science'.

Here, the conceptual problem is how to define the core of science and related social professional norms. The delineation between science and its application in the latest fields of biotechnology is often hard to make. Furthermore, interpretation of scientific results in a broader scope of society is often problematic. If law simply codifies or acknowledges the science of today, it often contributes to enlarging the fallacies of current scientific paradigms. As a result, scientific determinism and inevitable reductionism may end up extending biologism and shrinking persons to a simple mass of cells and tissues.

Interpretation of scientific discoveries has many traps. Bioethical analyses are not necessarily based on an accurate assessment of scientific developments, and these interpretations sometimes misread the effects of applying new biotechnologies. Moreover, normative interpretations may also be distorted due to factors that are entirely independent from scientific research. Judicial interpretations, then, must analyze scientific activities in a complex way and separate scientific advances from commercial interests, to peel off the legacy of an older, paternalistic professional tradition, and to deflect eugenic and reductionist thinking. In this complex work, bioethics may offer some help.

As we have seen, reproductive and regenerative medicine is an especially contested field for constitutional interpretation. The vast quantity of data and the ever-growing body of knowledge produced by the Human Genome Project and the various biobank programs provide important resources for scientific analysis and have led to the development of a wide range of therapies. Stem cell research opens up new vistas not only for prolonging the human life-span but also for offering new types of reproductive services to those who need them.

These new biotechnologies represent serious challenges to constitutional concepts and often require new interpretations of human dignity, bodily self-determination, identity and parenthood, notions of person and reproductive rights, principles of data protection and consent, and the boundaries of the body and personhood. Existing constitutional frameworks and accepted bioethical principles seem to provide answers in classical frontiers of life cases but remain insufficient and inconsistent when boundaries of personhood and the human body are concerned.

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