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2011 Round

University of Pavia, June 10th 2010

Edited by

Chiara Boscarato – Franco Caroleo – Amedeo Santosuosso



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Contents

Introduction

Chiara Boscarato, Franco Caroleo, Amedeo Santosuosso VII

Human Tissue in Three Dimensions: Material, Informational and “Human”

Matteo Macilotti 1

Post Traumatic Stress Disorder, Neuroscience, and the Law

Barbara Bottalico, Tommaso Bruni 19

Biobanks between Law and Technology: How to Promote Data Sharing in the Digital Era

Rossana Ducato 37

Genetic Tests “Direct-to-Consumer”: From “Informed Consent” to “Informed Will”

Patrizio Ivo D’Andrea 55

Biosimilars Regulation between Safety and Economic Concerns: A Comparative Analysis

Matteo Dragoni 73

Drug Courts between Therapeutic Jurisprudence and Neurolaw: Which Model of Addiction?

Sara Quiriconi 91

Synthetic Biology and Human Rights in Europe: A Comparison between the EU and the Council of Europe Systems, in the Field of Health and Environment

Daniele Ruggiu 111

Changing the Criminal Character: Nanotechnology and Criminal Punishment

Katrina Sifferd 129

Biobanks, Patents & Intellectual Property Rights (IPR): A Comparative Study of the US & Europe from the Perspective of India	
Vishal Vijayvargiya	153
Cryopreservation of Embryos: The Italian Situation in a European Perspective	
Cecilia Zorzoli.....	169

Introduction

This volume contains the materials of the “Law&Science Young Scholars *Informal* Symposium – 2011 Round”. The event is the only one of its kind and is intended by the Interdepartmental Research Centre “European Centre for Law, Science and New Technology” (ECLT) to be a constant reference point in ensuring that the focus on young researchers (which has been the subject of much but not always fruitful discussion) may be maintained within the scientific and academic communities.

ECLT, instituted by the University of Pavia in 2004 under its previous name of “European Centre for Life Sciences Health and the Courts” (ECLSC), studies issues relating to the connection between law, science and new technologies from an international perspective.

The Centre pays particular attention to those young people who are just starting off in the world of academic research. A young scholars’ session is, therefore, always one of the numerous events organized by the ECLT, offering them the opportunity to become involved in institutional conferences alongside well-known experts.

The idea of organizing one single day completely for young people came about in 2010 and was followed, within a few weeks, by the first edition of the Symposium, aimed at Italian researchers. Researchers responded with enthusiasm and papers of an extremely high standard were submitted.

The 2011 event started off from the same idea and built upon it, also thanks to the precious collaboration of the Collegio Ghislieri, Istituto Universitario di Studi Superiori (IUSS) of Pavia and the Fondazione Maugeri of Pavia (which funded the “Fondazione Maugeri Prize”). The 2011 Symposium also took on an international dimension (with the decision to have English as the sole working language) so that young scholars would have the chance to work directly with colleagues from around the world.

The aim of the “2011 Law & Science Young Scholars *Informal* Symposium” was therefore to be both an institutional and an informal forum within which young researchers (post-graduate researchers, Ph.D. students, post-doc students or early-career researchers in general) in the field of Law&Science could discuss their research results, meet other young scholars in the sector, enjoy the experience of participating in a conference and publish their papers.

Special attention was paid to the participant selection procedure. An international commission of legal and scientific experts examined candidate proposals by double anonymous crossed revision. Each abstract was evaluated by three referees, one scientist and two lawyers (not the same nationality as the candidate). The full papers of the admitted abstracts were reviewed by three different referees. At both stages each candidate received the referees’ observations on the strong points of his/her work and some advice on how to improve weak areas, thus obtaining precious and authoritative feedback. The names of the referees and the details of the selection procedure were published on the ECLT website page on the event (<<http://www.unipv-lawtech.eu/lang1/2011->

law---science-young-scholars-informal-symposium-and-prize---pavia.html>) along with a short report.

The morning and afternoon sessions opened with a Keynote Lecture from an eminent scholar. It was a real honour for the ECLT and the University of Pavia to welcome John Searle, Professor of Philosophy at the University of California, Berkeley, one of the most important living philosophers and widely noted for his contributions to the study of the philosophy of language and of the mind. The scientific Keynote Lecture, given by Orsetta Zuffardi, Professor of Medical Genetics at the University of Pavia, addressed the most hotly-debated issues in current genetic research.

By way of further recognition for young scholars, the two best papers were awarded a money prize by the Fondazione Salvatore Maugeri, the “Fondazione Maugeri 2011 Law&Science Young Scholar Prize” while the third best paper received a special mention.

The three best papers constitute the first three chapters of the volume, in the order of classification achieved. Other contributions are presented in the alphabetical order of the authors’ names.

We would like to thank the academic institutions of Pavia and everyone who made this event possible.

Chiara Boscarato, Franco Caroleo, Amedeo Santosuosso*

* Chiara Boscarato and Franco Caroleo, Ph.D. students at the University of Pavia were responsible for the scientific organization of the event. Amedeo Santosuosso is the President and one of the founders of the ECLT.

Human Tissue in Three Dimensions: Material, Informational and “Human”

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Abstract: In my paper, I discuss the legal status of human biological materials (hereinafter HBMs) removed from the human body. I argue that HBMs could be viewed from three different perspectives – material, informational, and ethical – which “generate” different, overlapping “bundles of rights”. For this reason I suggest the adoption of a new overall vision, able to encompass all three perspectives, for understanding the legal status of HBMs.

The overlapping of the three dimensions causes a conflict that prevents a meaningful analysis of each dimension separately. The only possible way to understand the legal status of human tissue is to adopt a three-dimensional vision and focus the attention on the relationship between the dimensions. The aim of this paper is to carry out a deep analysis of these relationships in order to propose a new model of the legal nature of human tissue.

Contents: 1. Introduction - 2. The Legal Status of Human Biological Materials - 2.1. The Material Perspective - 2.2. The Informational Perspective - 2.3. The “Human” Perspective - 3. The Three Dimensional Nature of HBMs - 4. Conclusion - References

1. Introduction

The definition of the legal status of human biological materials (HBMs)¹ has always been a hotly contested issue². This issue is even more pressing in the context of current biomedical research in which the demand for HBMs is constantly rising. In fact, HBMs represent an irreplaceable source of biological and genetic data, useful for implementing new genetic tests, therapies and medicines.

In this context, there has been an explosion of debates about the ownership of HBMs and their commercialisation³, which in turn is closely linked to the definition of the legal status of human tissue. If, in the past, this debate had only theoretical consequences, today its practical effects are striking⁴. Indeed, the clarification of the legal status of human samples is crucial in determining who can perform scientific research on them, to what extent and within what limits. This choice involves many stakeholders: individuals⁵, researchers, biotechnology companies, health care systems (etc.), and every stakeholder has “some good reasons” for claiming the some rights on HBM.

Patients have an interest in keeping some control of the flow of their personal data, in deciding on the ways in which their body parts can be used and, eventually, in knowing ensuing information that could be of pertinence to their health. Researchers have an interest in using HBMs in their research and an interest in knowing as many data as possible. Biotechnology companies have an interest in using the samples for genetic test and drugs testing (etc.). This list is not exhaustive and it shows that the assignment of rights over HBMs is the result of a complex evaluation that is carried out within different national legal systems, and it depends on the balance of interests that each legal system aims to promote⁶.

Moreover, as it will be clarified in the following section, current reflection about the rights on HBMs is deeply influenced by technology. Thanks to today’s technology, human samples are not considered only as aggregates of molecules, but they primarily represent a source of personal, health and biological data. Therefore, it is possible to

¹ The terms “human biological materials” or “human tissue” are used to describe various types of different tissues. Every kind of bodily tissue has some particular features. From a legal point of view, it is not the same thing to speak about blood, urine, sperm, hair or a piece of spleen. See Hoppe N. (2009), *Bioequity – Property and Human Body*, Ashgate, p. 47. In this paper, when using the term “human biological materials” or “human tissue”, I refer to tissue separated from the human body during surgery and subsequently used in scientific research.

² Rao R. (2007), “Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?”, *The Journal of Law, Medicine & Ethics*, 35(3), p. 371; Hardcastle R. (2007), *Law and the Human Body. Property Rights, Ownership and Control*, Hart Publishing, p. 1; Magnusson R.S. (1998), *Proprietary Rights on Human Tissue*, in Palmer N., E. McKendrick (eds.), *Interest in Goods*, London, p. 25.

³ Charo R.A. (2006), “Body of Research – Ownership and Use of Human Tissue”, *N. Engl. J. Med.*, 15, p. 1517.

⁴ Bjorkman B., S.O. Hansonn (2006), “Bodily Rights and Property Rights”, *Journal of Medical Ethics*, 32, p. 209.

⁵ Hardcastle R. (2007), The author suggests four situations where having a power of control may be significant to an individual: “(a) Individuals may wish to determine the forms of scientific and medical research for which their biological material are used; (b) Individuals may not wish separated biological materials to be used in a commercial setting; (c) Individuals may not wish separated biological materials to be immortalized (i.e. cell line); (d) Control of biological materials may be significant for individuals when such materials are used to obtain personal genetic information”.

⁶ Tallacchini M. (1998), “Il corpo e le sue parti. L’allocazione giuridica dei materiali biologici umani”, *Medicina e Morale*, 3, p. 499.

consider one's relationship with human tissue from two distinct viewpoints: the first one has to do with one's relationship with the data, and the second is one's relationship with the materials⁷. Moreover, in the case of human tissue there is another perspective seems to be relevant, that we could call "human" perspective. This perspective is based on the idea that the origin of tissue from the person is not neutral. Indeed, there are some legal norms that forbid some uses of tissue not for privacy or property protection but because they could violate the dignity of human being.

The first part of the paper will be dedicated to a brief analysis of the characteristics of these three perspectives. In the second part we will analyze how these three perspectives are related each other. We will see that the overlapping of the three dimensions causes a conflict that prevents a meaningful analysis of each dimensions separately. The only possible way to understand the legal status of human tissue is to adopt a three-dimensional vision and to focus the attention on the relationship between the dimensions.

2. The Legal Status of Human Biological Materials

The definition of the legal nature of human tissue, the related issue regarding the relationship between human tissue and person, and the careful scrutiny of the interests at stake represent fundamental points in dealing with biobanks. Sometimes we automatically extend the rules that govern research on human body with regard to human tissue as if human tissue and human body were the same thing⁸. But, once removed from the body, human tissue could be considered as autonomous and independent entities. We cannot conflate the status of the human body as a whole with the legal status of human tissue as detached from the body⁹. We should resist the temptation of automatically applying the umbrella of "bodily integrity" rights to justify control over human tissue¹⁰.

The protection of human bodily integrity has its origin in the individual's right of self determination on his/her health. As we will come to appreciate in this section, in the case of human tissue detached from the body, the interests protected have a different origin, as do the possible harms that derive from their use.

In particular, if the protection of bodily integrity rights is the source of a person's power to consent or not to the detachment of his/her tissue from his/her body, these

⁷ Macilotti M. (2008), "Proprietà, informazione e interessi nella disciplina delle biobanche a fini di ricerca", *Nuova giur. Civ.*, 7-8, p. 223.

⁸ See the Council of Europe Recommendation Rec(2006)4 on "Research on Biological Material of Human Origin" which, dealing with obtaining biological material for research, states that "information and consent [...] should be as specific as possible with regard to any foreseen research uses and the choices available in that respect". The Recommendation seems to adopt a perspective that implies that each piece of biological material is recognized full (individual) rights and full control indefinitely.

⁹ Hardcastle R. (2007), p. 147. The author points out that "once X is separated from A, a physical object is created that is no longer an intrinsic aspect of A. As a result, X cannot be protected under the umbrella of the rights to bodily integrity. The tort of battery only protects physical invasion of the human body as whole".

¹⁰ See Knopper B.M., M. Hirtle (1996), "Banking of Human Materials, Intellectual Property Rights and Ownership Issues: Emerging Trends in the Literature International Policy Positions", *Law and the Human Genome Review*, 5, p. 96; Rodotà S. (2006), *La vita e le regole. Tra diritto e non diritto*, Milano, p. 81.

rights cannot be considered to be the basis for that person's control over his/her human tissue once removed from his/her body¹¹. Research procedures or other interventions carried out on tissue would never affect directly the health of the person from which they were separated¹².

This does not mean that human tissue does not constitute a particular type of "goods"¹³; it means that human tissue has peculiar features when compared with the human body as whole. If, in the case of the human body, we could maintain that "we are" our body and "we have" our body, in the case of human tissue, this statement is not completely valid¹⁴.

For these reasons, the challenge today is to define the legal status of human tissue as an autonomous entity, and to identify the complexity that applies when tissue is detached from the human body.

In the next pages, we will observe that human tissue can be seen via three different perspectives: the material, the informational and the "human" one. The crucial point to retain is that these three perspectives cannot be considered separately, because they overlap. Therefore, in the analysis of the legal status of HMBs it is necessary to adopt an overall approach able to consider the effect of this overlapping.

2.1. The Material Perspective

Historically, when technology did not permit us to fully appreciate the informational capacity of human tissue, tissue was considered simply as an aggregate of molecules, a chemical entity¹⁵. It followed naturally for scholarly and jurisprudential reflection about the legal status of human biological materials to focus on the material nature of tissue.

¹¹ See Knopper B.M., M. Hirtle (1996), p. 96. They underline that the "personal rights approach" finds its origin in the relation that tissue "maintains with the person from whom it originated that warrants that the integrity of the person still applies to the material once removed from the body. In a personal rights approach, an individual right to integrity includes respect for bodily material once removed from the body and still identifiable to that person. The mechanism employed to ensure respect and protection of the integrity of the person and of bodily material is informed consent".

¹² See Grubb A. (1998), "I, Me, Mine": Bodies, Parts and Property", *Medical Law International*, 3, pp. 299-300. The authors remarks there is a distinction between rights relating to the taking of body parts and rights relating to the use and control of body parts: "English law has developed in the last decade to provide significant protection to individuals' self-determination by recognizing a 'right of bodily integrity' such that the taking of any tissue from a competent adult person would be unlawful without the consent of the source. The law is, however, solely concerned with the "taking" rather than the "use" of extra-corporeal organs or tissue. By contrast, property law would have something to say about subsequent 'use' and 'control'".

¹³ The main consequence of this assertion is that we have to distinguish research on human body from research on human tissue, and that we cannot automatically apply the rules that govern research conducted on human body in the case of human tissue.

¹⁴ These characteristics could justify, for instance, the different rules applied in "informed consent" for research on human tissue and for research on the human body, respectively.

¹⁵ Seenev B.E. (1998), "Moore 10 Years Later – Still Trying to Fill the Gap: Creating a Personal Property Right in Genetic Material", *New Eng. L. Rev.*, 32, pp. 1131-1132. The author points out that "Before there were biotech-companies, recombinant DNA, or Western Blots, the only interest in the body was the interest in the dead corpse". Seenev recalls the sentence of Sir Edward Coke who stated that "*the buriall (sic) of the cadaver (that is caro data veribus) is nullis in bonis, and belongs to ecclesiastical cognizance*" Coke E. (1644), *Institutes of the Laws of England*, p. 203.

For this reason, scholars never seriously questioned whether tissue could be seen as *res*, and therefore as potentially subject to property rights. The issues thought to be relevant at that time were issues such as the terms of property acquisition and ownership post-detachment.

Whilst an in depth discussion of the different theories about acquiring property rights over samples is beyond the scope of this paper, it is interesting to refer briefly to some characteristic examples. In Italian law, for instance, we can identify four main theories, starting from the hypothesis of the so-called “separation”¹⁶. Firstly, detachment transforms biological material into a thing potentially subject to property rights, and secondly, detachment creates property rights in the separated biological material¹⁷. According to this interpretation, at the moment when tissue is removed from the donor, the individual from whom the material is taken is still considered to be the immediate owner.

Another recurrent doctrine is the hypothesis of “occupation”, according to which tissue removed from the human body, once separated, would be comparable to the legal concept of *res nullius*, or goods that are the property of no one. According to this theory, it is presumed that tissue is abandoned at the moment of its removal with the consequence that whoever possesses it becomes their owner.

A third hypothesis identifies a parallel between the rights of removed tissue and the ideas. According to one legislative interpretation, in the same way in which an individual is the owner of their own ideas, they would also be considered the owner of their own biological tissues (article 2576 Italian civil code). According to this legal position, removed tissue is still the property of the patient, even if they were removed with the help of a surgeon. There are also those that consider removed tissues as “natural fruits”, or “fruits” that are produced directly from the owner’s body, eventually with the help of someone else, in this case, a surgeon¹⁸.

To consider human tissue as a thing that can be the object of property, is not a position that is foreign to common law experience¹⁹. There has been a distinct reluctance on the part of the “common law” courts to address the issue of the capability of tissue to be owned, and we have only few cases that can help us. The first case is a judgment of the Australian High Court in *Doodeward v. Spence*²⁰, in which the body of a still-born two-headed baby was preserved in spirits by the doctor who had been attending its mother.

¹⁶ This theory is widespread not only in the Italian legal system but also in other common law and civil law contexts. See Whitty N.R. (2005), “Rights of Personality, Property Rights and the Human Body in Scots Law”, *Edinburgh Law Review*, 9, p. 194-199. The author suggests that the detachment of biological materials is a sufficient act to create property rights.

In the common law context see also: Hammond C. (2002), “Property Rights In Human Corpses and Human Tissue: The Position in Western Australia”, *University of Notre Dame Australia Law Review*, 4, pp. 97-113; Dworkin G., I. Kennedy (1993), “Human Tissue: Rights in the Body and Its Parts”, *Medical Law Review*, 1, pp. 291-311; Dickens B. (1977), “The Control of Living Body Materials”, *University of Toronto Law Journal*, 27, pp. 142 -183.

¹⁷ See Hardcastle R. (2007), p. 146.

¹⁸ Criscuoli G. (1985), “L’acquisto delle parti staccate del proprio corpo e gli art. 820-821 c.c.”, *Riv. dir. fam.*, 14, p. 271.

¹⁹ Grubb A. (1998), p. 300.

²⁰ *Doodeward v. Spence*, High Court of Australia, (1908) 6 CLR 406.

Upon the doctor's death it was sold and later came into the possession of another person (C), who exhibited it for profit as a curiosity. A police officer then seized the body with a view to its burial. C's action for detinue succeeded. Chief Judge Griffith said: "[W]hen a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it...". According to the Australian court, body parts *per se* are not capable of being owned, unless there has been some activity that differentiates them from a mere corpse.

Following the *discrimen* drawn in *Doodeward*, the English courts have established the principle that there can be no ownership in a human corpse. In the case of *Dobson v. North Tyneside Health Authority*²¹ the Court of Appeal held that the fixing of tissue (in this case the brain) in paraffin had not been on a par with preserving it for future use as a commercial exhibit (like in *Doodeward*); and as a consequence it could not be considered as an object of "property".

The same principle was confirmed in *R. v. Kelly*²². Nevertheless, relevant for our issue, it should be noted that the court speculated in this case that – despite 150 years of common law confirming that neither a corpse, nor parts of a corpse, can in themselves be capable of being property – things may eventually change. Lord Justice Rose remarked that:

[T]he common law does not stand still. It may be that if, on some future occasion, the question arises, the courts will hold that human body parts are capable of being property (for the purposes of section 4), even without the acquisition of different attributes, if they have a use or significance beyond their mere existence. This may be so if, for example, they are intended for use in an organ transplant operation, for the extraction of DNA or, for that matter, as an exhibit in a trial. It is to be noted that in *Dobson's* case, there was no legal or other requirement for the brain, which was then the subject of litigation, to be preserved.

As has already been underlined, the development of technology has conferred upon tissue a value that cannot be underestimated. If in the past mere body parts could not acquire some value without the acquisition of different attributes, today, in the biotechnology era, tissue have a value *per se*, and "*a use or significance beyond their mere existence*". This aspect can change, quite fundamentally, the nature of the tissue. The property interests related to tissue can therefore be considered as a basis for a "*revirement*".

A first shift in the traditional non-property rule towards a possible *revirement* is represented by the *Yearworth* case, though it would be incorrect to derive from this case a general rule by virtue of which tissue became capable of being owned. The case

²¹ *Dobson v. North Tyneside Health Authority and Another*, [1997] 1 WLR 596. In carrying out a post mortem examination on a woman who had died of a brain tumour a pathologist removed her brain and fixed it in paraffin, pending a possible further examination of it which in fact was never conducted. It was delivered to D2's hospital for storage. The rest of the woman's body was buried. Two years later the next of kin sought to examine the brain for the purpose of securing evidence supportive of their action in negligence against D1. The brain could not be found so they sued D2 for having destroyed or mislaid it. Their appeal against the striking out of their action against D2 was dismissed.

²² *R. v. Kelly and Lindsay* [1999] Q.B. 621.

concerned Mr. Yearworth and the five other claimants, all of whom had been diagnosed with cancer and had undergone chemotherapy treatment at Bristol Southmead Hospital. Since the hospital had a fertility unit licensed under the Human Fertilisation and Embryology Act 1990, the men were offered the option to have samples of their semen frozen and stored for use at a later date, due to the potential damaging effect of the chemotherapy on their fertility. Acting on the advice received, the six men produced samples for storage. Each of the claimants had consented to the storage of their semen for ten years, the maximum allowable time under the 1990 Act. The storage system at the hospital failed, and as a result the men's semen thawed and the sperm contained therein was irreversibly damaged. In the judgment of the English Court of Appeal, Lord Judge recognised that “*the sperm was the property of the men for the purposes of their claims in tort and, as amended, in bailment and that they are in law capable of recovering damages for psychiatric injury and/or mental distress in bailment*”.

Unlike the English courts, the American courts have not rejected the idea that tissue is a *res* capable of being owned. Even if it is in a different context, we can also find – in the statement of the US Court of Appeals for the Eighth Circuit, in the famous case involving Professor Catalona – the idea that samples detached from the human body are things²³, in which the person who has undergone the detachment can be considered as owner. Indeed, the Court of Appeals agrees with the Trial Court²⁴, and endorses the assertion that patients “donated their biological materials to WU as *inter vivos* gifts”. But the logical (not clearly expressed from the Court) premise is that the patient was the owner of the tissues and the tissues are things subject to property rights²⁵.

The idea of tissue as a property has its origin in the idea that after its detachment, the tissue becomes an entity completely separated from the person with no further connections. Following this idea it is possible to affirm that once X (tissue) is separated from A (person), a physical object is created that is no longer *an* intrinsic aspect of A²⁶.

If we consider human tissue only from this material perspective, the pertinent legal issues become issues of best allocation of property on such tissue. In this view, samples are a scarce resource and for the maximization of their value (e.g. from a scientific point of view), it is necessary to establish which allocation is the most efficient. In following this perspective, it is clear that the researchers (or the biotech and pharmaceutical company) could obtain useful information and useful products from their use of tissue, that, normally, the “donors” cannot extract from tissue due, for example, to lack of knowledge or equipment²⁷. This view could further lend support to justifying a sort of

²³ *William J. Catalona, M.D. v. Washington University*, 8th U.S. Circuit Court of Appeal, Nos. 06-2286 & 06-2301, June 20, 2007.

²⁴ *Washington University v. William J. Catalona, M.D.*, United States District Court Eastern District of Missouri Eastern Division, No. 4:03CV1065, E. Dist. Mo. April 14, 2006.

²⁵ For an analysis of the meaning of the “genetic gift” and the possible inconsistencies between this concept and current regulatory views on property in the UK see Kanellopoulou, N. (2009), “Reconsidering Altruism, Introducing Reciprocity and Empowerment in the Governance of Biobanks in the UK”, in Kaye J., M. Stranger (eds.), *Principles and Practice in Biobank Governance*, Ashgate, pp. 33-36.

²⁶ Beylerveld D., R. Brownsword (2000), “My Body, My Body Parts, My Property?”, *Health Care Analysis*, 8, pp. 87-92.

²⁷ See § 32 of the Judgment of *United States District Court Eastern District of Missouri Eastern Division* in the Catalona case (supra n. 24), where the Court maintains: “If research participants who had contributed

“expropriation for public utility”. However, as remarked before, the “material perspective” is only one possible perspective and it exists in close connection with the remaining two perspectives examined below.

2.2. The Informational Perspective

Scientific knowledge completely revolutionised the material perspective by revealing the informational potential of tissue. Following the development of genetic studies and research-based technologies, human tissue started to be considered as a valuable source of medical and genetic data, contributing to the progress of medical science. These data contain useful information about patients, such as their health, biological identities, and their individual predispositions to specific diseases. From simple aggregates of molecules, tissues are considered as valued sources of data²⁸.

In their “informational dimension”, HBMs show different features to their “material dimension”. Human tissue and human bodies share the same information even after the tissue is separated from the body. Indeed, tissues contain the genome of the body they were removed from. Therefore, from an informational point of view, the detachment of human tissue from the human body does not imply the complete separation of the samples from the body of origin. It is no longer valid to assume what we previously asserted in the material dimension that “once X is separated from A, a physical object is created that is no longer *an* intrinsic aspect of A”. This is because X, even after the separation, is still an intrinsic aspect of A from the informational point of view²⁹. This fea-

biological specimen to a research institution could subsequently direct that their samples be transferred to a third party, then researchers could engage in unregulated proxy battles for human subject specimens, and research participants could sell their specimens to the highest bidder. Moreover, scientific research could be thwarted because collections of biological materials could not readily be kept and maintained. Defendants’ interpretation would balkanize large collections of biological materials, discourage investment in collecting and maintaining them, and promote instability at the expense of scientific progress”.

²⁸ As the recent case *Myriad* showed (United District Court for the Southern District of New York, *Association for Molecular Pathology et. Al. v. United States Patent and Trademark Office*, 09 Civ. 4515, March 29, 2010), this distinction has become relevant even in the case of patentability of DNA. Judge Sweet upheld the idea that DNA has a dual nature: it has a chemical form, but its value lies primarily in the information which it encodes. The Judge held that, as the value of the DNA was primarily informational, and as the information was the same in isolated and natural form, then the substance in question did not have markedly different characteristics and as a result was not patentable. See Hawkins N. (2010), “Human Gene Patents and Genetic Testing in Europe: a Reappraisal”, *Scripted*, 7(3), pp. 453-457.

²⁹ From a descriptive point of view, the double relationship between individuals and tissues and between individuals and the information related to the samples seems to share the same scheme. They follow the legal scheme known in the European Continental legal tradition as “subjective rights” (*droits subjectifs; subjektives Rechten*), a scheme that implies a subject of right and an object of right and both describe a relation of “belonging” (The term “belonging” is proposed here to describe a relationship that includes all possible relationships between a person and their samples. In the Italian literature, the word used to define this relationship is “*appartenenza*”). But there is a multitude of different levels of “belonging”, which could be represented as a planetary nebula (See Zatti P. (2007), “Il corpo e la nebulosa dell’appartenenza”, *Nuova Giur. Civ. Comm.*, II, p. 3). The legal concept of property, as derived in all continental legal systems from the Roman tradition, would be on the edge of this nebula: in the typical property relationship, it is implied and presupposed that owner and owned object are separate entities. One finds the highest level of “belonging” when the idea of separateness is absent, and the owner and the owned object are indistinguishable. This is also the case of “personality rights”, which are not distinguishable from the individual who holds the rights.

ture has important consequences at the legal point of view. If from the material perspective tissue represents a “res” completely distinct from the body, from the informational perspective even after the detachment from the body, tissue remains linked with the person.

This characteristic denies us the possibility of describing the relationship between person and his/her personal data through the conceptual apparatus of “property rights”. Indeed, in this case the owner and the owned object would be the same. In continental legal systems, the rights (that I will define in the next pages) over personal data are taken into consideration through the distinct conceptual category of so-called “personality rights”³⁰. These rights are included in this category because personal data are conceived as “objects” capable of depicting some aspect of our personality³¹. In some way, they represent to the outside world, some aspects of “what we are”. If personal data represent an expression of our personality, through a sort of abstraction exercise, we can reasonably affirm that to dispose of these data represents an expression of “self-determination”. Therefore, while from the material perspective to dispose of human tissue detached from the body means to determine the destiny of a thing external to the person, from the informational perspective it means to self-determine ourselves given that, even after the detachment, our tissue are still able to provide some information about us.

The point is to define which rights one person can claim in respect of the personal data deriving from tissue and if the right of self-determine ourselves through the control of our personal data is recognized. At the European level the right to protection of personal data represents a fundamental right and it is recognized by article 8 of the Charter of Fundamental Rights of the European Union³².

This right seems to have two distinct features. The first can be identified in the first paragraph of article 8 which establishes that “everyone has the right to the protection of personal data concerning him or her”. This cryptic statement implies the creation of a duty upon data controllers to only process personal data lawfully, and also to protect

In this view, the protection of personal identity, for instance – a typical personality right – is not a right that can be evaluated without considering the person to whom dignity refers: the two elements are inextricably linked one to another.

³⁰ This legal concept is shaped by the traditional idea of property, which implies an owner of rights who is an entity clearly separate from the object of the rights that this latter owns. See Coing H., F.H. Lawson, K. Gronfors (1959), *Das subjective Recht und der Rechtsschutz der Persönlichkeit*, Frankfurt am Main-Berlin.

³¹ Even though common law systems do not recognise “personality rights”, despite their widespread recognition in civil law systems, the relationship between the person and his/her personal information is generally not considered a property relationship in common law systems. Even if, in English law, the question as to whether personal information is capable of a proprietary characterisation is not settled, English Courts seem to reject the idea that the relationship between the person and his personal information could be classified as property. The reason is clearly explained by Paul Stanley who notes that the “English law does not impose duties upon people with respect to confidential information because it recognises some particular relationship between claimant and the information (a right *in rem*) which requires protection against strangers. Rather it imposes duties between individuals (rights *in personam*) whose consequence is to protect information”.

³² By virtue of the article 6 of the “Lisbon Treaty”, the “Charter of Fundamental Rights of the European Union” has the same legal value as the Treaties. It is important to underline that the Charter has limited effects for the Poland and UK by virtue of the “Protocol on the application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom”.

the data adequately. This duty represents the “passive side” of the protection of personal data and it is shaped by the classical concept of privacy as the right to freedom from intrusions from others in our “private life”³³. In the case of human samples, this rule implies a duty for those who retain the samples and the data deriving from samples, to adopt adequate security measures to prevent the unlawful use of the personal data and the samples, which are considered as a “physical vessel” in which data are stored.

But data protection does not only lie in the protection from such intrusions. There is a second feature of the right to protection of personal data that permits a person to play an “active” role. In part, this second feature is expressed in the second paragraph of article 8 of the Charter, which establish that “such data must be processed [...] on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified”. This norm introduces in the fundamental right of protection of personal data the possibility for the person to give his/her consent, to access to the data, to have it rectified. Therefore, the right of protection of personal data does not only consist in the edification of a “defensive wall” to prevent the unlawful use of the personal data, but it also includes the right to actively control the flow of these data. The rationale for this characteristic is found in the reasoning set out above about the relationship between person and his/her personal data, where we outlined that to dispose of these data represents an expression of “self-determination”.

This characteristic of the rights of data protection is most developed in the European continental legal tradition and the clearest expression of it could be found in the so-called right of “informational self-determination”, first coined by the German Federal Constitutional Court³⁴. It represents the right to decide what shall be disclosed about us, and to control our “external image”, through the control of our personal information. The logical corollary of this right is a series of specific rights relating to personal data, such as the right to express the consent, the right to access to the data, the right to withdraw the consent.

In the context of our analysis, these rights imply that the person has the possibility to control personal data derived from the tissue, and to change their mind. But given that tissue “contain” these data, this right implies the control over the tissue too. There-

³³ See Whitman J.Q. (2004), “The Two Western Cultures of Privacy: Dignity versus Liberty”, *Yale L. J.*, 113, pp. 1151-1160. The Author asserts that “At its conceptual core, the American right to privacy still takes much the form that it took in the eighteenth century: It is the right to freedom from intrusions by the state, especially in one’s own home”. While in Europe the core of privacy protection is the dignity of the person.

³⁴ The term “informational self-determination” was first used by the German Federal Court Constitution in the Judgment/ BVerfGE 65,1, at para. 154 of December 15, 1983. The Court stated that under Articles 1 and 2 of the Grundgesetz an individual has “the authority to decide for himself, on the basis of the idea of self-determination, when and within what limits facts about his personal life shall be disclosed.” See Kommers D.P. (1997), *The Constitutional Jurisprudence of The Federal Republic of Germany*, p. 324 (2nd ed.). See also, the Spanish Constitutional Court Judgements/SSTC 290/2000 and 292/2000, of November 30, 2000. In particular, the Spanish Constitutional Court Judgement 292/2000 recognized for the first time the right to the protection of personal data as an autonomous right. See also the Italian Code for Person Data Protection, (Legislative Decree 196/2003).

fore this second aspect of the right of the protection on personal data invests in the person a continuing power of control over the tissue, even after the transfer of the tissue to third parties.

The bi-dimensional nature characterising human tissue, both considered as a molecular aggregate and as a source of data, represents one of the greatest challenges in the definition of the relationship between individuals and removed tissue. As we will see, this challenge depends on the fact that in the case of human tissue, these perspectives overlap inextricably.

2.3. The “Human” Perspective

In addition to the two perspectives just analyzed – material and informational – it is necessary to consider another level when assessing the “personal relationship” between human tissue and the human body, which could add depth to our analysis. This perspective (we could name it “human”) has a completely different nature from the others two just considered above and has its origin in the derivation of human tissue from the person³⁵.

This perspective originates from the idea that derivation of human tissue from the person cannot be neutral. Human tissue can be considered to be an particular *res* compared to the other chattels, characteristic which not only depends on the fact that tissue is a source of personal and genetic data, but also because it is ontologically peculiar due to its derivation from human body. This “ontological” peculiarity can be based either on religious belief or an “anthropological” vision of body parts, which awards a particular significance. In some cultures, for instance, the body and its parts are considered to be sacred. In other cultures, even after the detachment, body parts are considered to have the same “value” as the body as a whole.

While the material and the informational perspectives are “intrinsic” features of human tissue, the existence of this last perspective depends on the individual’s “ideas” about the relationship between human body and tissue detached from the body, it is therefore conditioned to their beliefs.

Similarly to the informational dimension, the “human” perspective persists after tissue is detached from the body, and, unlike the informational dimension, it remains even after anonymisation of that tissue. The anonymisation does not change the origin of tissue. Even if anonymised, tissue maintains its “human” origin³⁶.

This perspective is ambiguous and its impact on the policies adopted by the legislators is not easy to evaluate. A legislator can adopt two possible strategies for dealing with this perspective: (a) he could not take this perspective into account at all; (b) he

³⁵ Laurie G. (2002), *Genetic Privacy, A Challenge to Medical Legal Norms*, Cambridge University Press, p. 302. Previous scholars alluded to that nature when maintaining that “the moral significance of body parts remains even when they are separated from their original source”.

³⁶ See Kirchhoffer D.G, K. Dierickx (2011), “Human Dignity and Human Tissue: A Meaningful Ethical Relationship?”, *J. Med Ethics*, p. 5. The Authors underline that “even if the samples are anonymized, human dignity is still implicated”.

can recognize the existence of this perspective by giving the possibility to the individual to decide which value to assign to his/her tissue. In the latter case, the legislator does not establish what is morally wrong in relation to particular uses of human tissue, but it merely safeguards the person's possibility to express their choice as regards such uses.

The main instrument for the implementation of this strategy can be informed consent. Through consent an individual can choose if research on his/her tissue is compatible with his/her beliefs. An example is found in the 26th recital of Directive 98/44 EC for the Legal Protection of Biotechnological Inventions, which establishes that “whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law”³⁷. With this rule, the legislator does not establish that patents on human tissue are wrong nor does he protect the Informational Perspective or the privacy of the person but he recognizes the “human perspective” and enables the person, from whose body the material is taken, to express his/her beliefs about the “morality” of the patent developed from his/her tissue³⁸.

3. The Three Dimensional Nature of HBMs

The material, the informational, and the “human” perspectives are not completely separable, and the bundles of rights deriving from them are in part overlapped.

The first example of the overlap between the material perspective and the informational perspective is represented by the Italian legislation on the use of genetic data in medical research. According to the General Authorisation of the Italian Privacy Authority³⁹, tissue must be destroyed whenever the consent of a donor for the processing of genetic data in medical research is withdrawn. The only exception is where a sample cannot be linked to an identified and/or identifiable individual, either before or after it is processed by researchers. Through the operation of this rule, the material perspective comes into conflict with the informational perspective, inasmuch as when a person withdraws their consent for the use of data, even the tissue, in its material dimension, should be destroyed. Even if we could establish that the researchers own the tissue, a person's right to withdraw the consent as regards the use of genetic data would “over-

³⁷ For instance, in Italy this rule has been encompassed in the Industrial Property Code. The article 170 *ter* of the Code imposes an administrative fine (ranging from € 100,000 to € 1,000,000) on those who seek to patent inventions that involve the use of human tissue, without the explicit consent of the person”.

³⁸ The problem of this rule is that the object of the patent is not the tissue, *per se*, but the invention developed from the tissue.

³⁹ Italian Privacy Authority, *General Authorisation for the Processing of Genetic Data*, 22 February, 2007. See § 6: “In compliance with sections 23 and 26 of the Code, genetic data may be processed and biological samples used exclusively for the purposes specified herein, on condition that the person concerned has provided his/her written informed consent thereto [...]. Where a data subject withdraws his/her consent to the processing of data for research purposes, the biological sample will be also destroyed providing it has been collected for such purposes – except where the sample may be related no longer to an identified and/or identifiable individual either from the very beginning or because of the processing.”

rule” the property rights of the researchers over the tissue. The material dimension is therefore absorbed in the system of data protection. The biological sample is viewed as a “physical vessel” containing data, and little space is left for consideration of the biological material in terms of a property right.

The same view is proposed by the Council of Europe’s Recommendation Rec(2006)4 on “research on biological materials of human origin”. Article 15 of this Recommendation establishes that “when a person has provided consent to storage of identifiable biological materials for research purposes, the person should retain the right to withdraw or alter the scope of that consent. [...] When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner foreseen by national law, the materials either destroyed or rendered unlinked anonymized”. In the two proposed cases, the only way for avoiding the destruction of human samples is through their complete anonymisation. As such, the anonymisation is conceived as a strategy for deleting what it is “personal” in human tissue, and thus cutting the personal relationship between the person and the tissue. But this approach shows some weaknesses.

For one, it restricts the personal relationship over human tissue to the confines of privacy protection. But, we have already noted that, following the “human perspective”, there are other “ethical” instances that may need to be taken into consideration. Indeed, according to this approach, it seems that if the tissue is anonymous, it loses its “human” nature.

Moreover, the anonymisation appears merely a rhetorical fiction⁴⁰, useful for denying the personal interest on human tissue⁴¹. This fiction takes its origin from the idea that the shifting of the regulation of human tissues under the umbrella of “personal data protection” is valid inasmuch as the data derived from human samples can be considered personal. In order to be considered as “personal”, data have to refer to a specific individual. Clearly, if data are anonymised so that they cannot lead to the identification of one specific individual, there would no longer be any need to grant protection to the personal identity of the human being from whom those same data are extrapolated. If data and tissue are no longer personal, tissue becomes a “res”: the watershed being the possibility to link tissue with an individual.

But we could offer two criticisms of this legal solution. Firstly, we have to emphasise that it is impossible to attain the absolute anonymisation of human tissue. The deletion of the vital statistics does not preclude the abstract possibility of re-identifying indirectly the person to whom the tissue refers. For instance, through the use of DNA profiling techniques it is possible to use DNA collected from human tissue – even very small amounts – to distinguish one person from another. Moreover, it is possible to use DNA taken from a tissue sample to create a unique genetic “barcode”. Clearly, without

⁴⁰ Tallacchini M. (2003), *Retorica dell’anonimia e proprietà dei materiali biologici umani*, in D’Agostino F. (ed.), *Corpo esibito, corpo violato, corpo venduto, corpo donato. Nuove forme di rilevanza giuridica del corpo umano*, Milano.

⁴¹ The personal interest in human tissue is not only in the privacy protection. For instance, virtually everyone if they donated a sample they would appreciate feedback on what the research using their samples had discovered or achieved. See Laurie G. (2002), p. 317.

further information, it is not possible to link this “barcode” with a specific, identifiable individual, but through the comparison with other identifiable tissue [and information] this potentially becomes achievable. Therefore, we could affirm that human tissue always contains “something personal”, and this characteristic distinguishes human tissue from the other types of “res”⁴². Secondly, following the “human perspective”, the anonymization does not change the “human” relationship with the tissue.

The second example concern the overlapping between the property perspective and the “human” perspective. It is represented by the 26th recital of the Directive 98/44 EC for the Legal Protection of Biotechnological Inventions mentioned above. This rule does not protect the property rights or the right informational self determination of the person from whose body the material is taken, but it seems to follow an “human” perspective, according to which even after the detachment, a particular relationship between the person and their tissue remains. As a result, even if we could consider the researchers as owners of tissue, to patent an invention based on the biological material, the person from whose body the material was taken must give the opportunity of express his consent. It is clear that the bundle of property rights meets some limits in this instance.

If the three perspectives of human tissue overlap in some way then we cannot consider them as distinct concepts when seeking to understand the legal status of human tissue; instead it becomes necessary to analyse the tissue as a complex unit. Indeed, human samples represent a peculiar “res”⁴³, and the balancing of all three perspectives must be given due consideration in order to be confident that they can be used legitimately. Clearly this balancing exercise will change from State to State and will depend upon which interests each State intends to promote. In some legal orders, for instance, the interest in the scientific utility of human tissues for the progress of human biotechnology could prevail. In this case the property rights would be allocated to the researchers and the rights of the person over their tissue would likely be considered less relevant. In particular the right to privacy would be viewed as a sort of passive right, according to which the researchers would have an obligation to ensure confidentiality when they use human tissue, but there would be no recognition of a real power of control for the individual over their biological identity. In other legal orders the personality rights and the “human” perspective in the use of human tissue could be emphasised. In

⁴² An example could better clarify this concept. If I lost my T-shirt, there is nothing in the material constitution of the T-shirt’s cotton that can establish a link between me and my T-shirt. But, if I “lose” part of my tissue, the material constitution of the tissue is such that it can potentially be linked to me.

⁴³ The idea that corporality represents something different for a normal res that can be object of property, and the idea that it’s necessary to consider the role of the body in the formation of identity have brought some scholars to propose the quasi-property solution. See Bray M.B. (1990), “Personalizing Personality, Toward a Property Right in Human Bodies”, *Tex. L. Rev.*, 69, pp. 209-239. The authors concludes that “Recognizing a quasi-property right – the right of use and control, but a limited right of disposition – in both dead and living bodies is a coherent approach to according individuals the necessary control over their own bodies while protecting against the risk of commodification. Such an approach is also consistent with much of existing jurisprudence. The benefit of employing personhood analysis in arriving at the quasi-property right is the utilization of a philosophy that can adapt to address new legal issues as they arise, instead of simply attempting to force new dilemmas into existing legal parameters”.

this case, the bundle of property rights would suffer more restrictions and the use of human tissue could be subjected to a permanent control of the donors.

4. Conclusion

To define the legal status of human tissue is a complicated task. Sometimes it seems that we cannot resist the temptation to extend the rules that govern the human body to human tissue, as if s if they were one and the same. But the detachment of tissue from the body gives rise to a peculiar situation in which the nature of tissue changes compared to the human body.

The legal nature of tissue can be seen through three different perspectives: the material, the informational, and the “human”. Every perspective has its own features, and every perspective influences the other. For this reason, the only possible way to understand the legal status of human tissue is to adopt a three-dimensional vision and focus our attention on the relationship between these dimensions⁴⁴.

⁴⁴ Marie Curie Cofund Fellow Researcher, University of Trento. This paper has been developed in the project “Trentino-PCOFUND-GA-2008-226070” granted by Autonomous Province of Trento and the European Commission”.

References

- Beylveid D., R. Brownsword (2008). "My Body, My Body Parts, My Property?". *Health Care Analysis*, 8.
- Bjorkman B., S.O. Hansonn (2006). "Bodily Rights and Property Rights". *Journal of Medical Ethics*, 32.
- Bray M.B. (1990). "Personalizing Personality, Toward a Property Right in Human Bodies". *Tex. L. Rev.*, 69.
- Charo R.A. (2006). "Body of Research – Ownership and Use of Human Tissue". *N. Engl. J. Med.*, 15.
- Coing H., F.H. Lawson, K. Gronfors (1959). *Das subjective Recht und der Rechtsschutz der Personlichkeit*, Frankfurt am Main-Berlin.
- Criscuoli G. (1985). "L'acquisto delle parti staccate del proprio corpo e gli art. 820-821 c.c.". *Riv. dir. fam.*, 14.
- Dickens B. (1977). "The Control of Living Body Materials". *University of Toronto Law Journal*, 27.
- Dworkin G., I. Kennedy (1993). "Human Tissue: Rights in the Body and Its Parts". *Medical Law Review*, 1.
- Gewirth A. (1996). *The community of rights*. University of Chicago Press.
- Grubb A. (1998). "I, Me, Mine': Bodies, Parts and Property". *Medical Law International*, 3.
- Hammond C. (2002). "Property Rights in Human Corpses and Human Tissue: The Position in Western Australia". *University of Notre Dame Australia Law Review*, 4.
- Hardcastle R. (2007). *Law and the Human Body. Property Rights, Ownership and Control*. Hart Publishing.
- Hawkins N. (2010). "Human Gene Patents and Genetic Testing in Europe: A Reappraisal". *Scripted*, 7 (3).
- Hoppe N. (2009). *Bioequity - Property and Human Body*. Ashgate.
- Kanellopoulou N. (2009). *Reconsidering Altruism, Introducing Reciprocity and Empowerment in the Governance of Biobanks in the UK*, in Kaye J., M. Stranger (eds.). *Principles and Practice in Biobank Governance*, Ashgate.
- Kirchhoffer D.G., K. Dierickx (2011). "Human Dignity and Human Tissue: A Meaningful Ethical Relationship?". *J. Med Ethics*, 5.
- Knopper B.M., M. Hirtle (1996). "Banking of Human Materials, Intellectual Property Rights and Ownership Issues: Emerging Trends in the Literature International Policy Positions". *Law and the Human Genome Review*, 5.
- Laurie G. (2002). *Genetic Privacy, A Challenge to Medical Legal Norms*. Cambridge University Press.
- Macilotti M. (2008). "Proprietà, Informazione ed interessi nella disciplina delle biobanche a fini di ricerca". *Nuova giur. Civ.*, 7-8.
- Magnusson R. (1998). *Proprietary Rights on Human Tissue* in Palmer N., E. McKendrick (eds.). *Interest in Goods*, London.
- Rao R. (2007). "Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?". *The Journal of Law, Medicine & Ethics*, 35(3).

- Rodotà, S. (2006). *La vita e le regole. Tra diritto e non diritto*. Milano.
- Seeney B.E. (1998). “Moore 10 Years Later – Still Trying to Fill the Gap: Creating a Personal Property Right in Genetic Material”. *New Eng. L. Rev.*, 32.
- Tallacchini M. (1998). “Il corpo e le sue parti. L’allocazione giuridica dei materiali biologici umani”. *Medicina e Morale*, 3.
- Tallacchini M. (2003). *Retorica dell’anonimia e proprietà dei materiali biologici umani*, in D’Agostino F. (ed.). *Corpo esibito, corpo violato, corpo venduto, corpo donato. Nuove forme di rilevanza giuridica del corpo umano*. Milano.
- Whitman J. (2004). “The Two Western Cultures of Privacy: Dignity versus Liberty”. *Yale L. J.*, 113.
- Whitty R.N. (2005). “Rights of Personality, Property Rights and the Human Body in Scots Law”. *Edinburgh Law Review*, 9.
- Zatti P. (2007). “Il corpo e la nebulosa dell’appartenenza”. *Nuova Giur. Civ. Comm.*, 2.

Post Traumatic Stress Disorder, Neuroscience, and the Law

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Abstract: PTSD is a complex psychiatric condition whose effects can be seriously debilitating. As it originates from a specific traumatic event, it often concerns soldiers and victims of violent crime. It is currently one of the most frequently litigated mental diseases. Neuroscience is slowly discovering the neural bases of PTSD and other psychiatric ailments and is building tests to distinguish actual patients from malingering individuals. We examine the current state of neuroscientific research on PTSD and its biomarkers, focusing on a recent experiment by Apostolos Georgopoulos and coworkers. Then we analyze the legal consequences of these scientific advances, both in civil and criminal law, under a comparative perspective. Neurotechnology is likely to provide courts with a new kind of evidence, which will not replace the older behavioral evidence, and to weaken the so far standing distinction between physical and emotional harm. However, even extremely sensitive tests (>95%) can have insufficient accuracy if the prevalence of a condition in the tested population is low. Therefore, the law ought to take into account the prevalence of PTSD and other psychiatric conditions when the decision whether to admit neuro-evidence in courts or not must be made.

Contents: 1. Introduction - 2. The Origin of PTSD: A Brief History - 3. Neuroimaging and PTSD - 3.1. The State of the Art - 3.2. Georgopoulos' MEG Experiments - 4. PTSD in Court - 4.1. The Legal Framework - 4.2. PTSD and Pain: The Subjectivity of Perception - 4.3. Neuroscientific Evidence in Civil and Tort Law - 5. Conclusion - References

1. Introduction

The consolidation of a traumatic memory forms the basis for Post-Traumatic Stress Disorder (PTSD). PTSD is defined by four main symptoms: (1) re-experiencing of painful memories, (2) effortful avoidance of trauma cues, (3) emotional numbing, and (4) hyper-arousal. The disorder arises from exposure to one or more potentially life-threatening events, such as childhood physical and sexual abuses, motor vehicle accidents, and natural disasters. Much of the neurobiological correlates of PTSD remain hypothetical or undetermined still today. This makes the legal assessment of this disorder complex.

The use of brain imaging techniques has recently allowed researchers to uncover some of the neural networks involved in PTSD. Two of the most recurrent findings in PTSD patients are decreased medial prefrontal cortex (MPFC) and increased amygdala activation.

In 2010, however, the team of A. Georgopoulos at the University of Minnesota used MagnetoEncephaloGraphy (MEG) to directly measure the magnetic fields produced by electrical activity in the brain of PTSD-affected war veterans and healthy controls. They examined the subjects in a task-free condition, seeking to spot differences in cortical communication in their steady-state brains. According to the team, steady-state MEG allows classification of PTSD patients and healthy subjects with an accuracy of about 90% through a recurrent MEG pattern in the right temporal lobe. If this result is replicated, there will be a reliable biomarker for PTSD. The intensity of the marker signal reliably correlates with the severity of PTSD symptoms in patients, so that severity assessment would be possible. As Georgopoulos himself maintains, further studies are needed to confirm these findings in other groups, such as children and non-veterans adults.

Comparing Italian, US and English legal systems, this paper analyzes how improvements in neuroscientific research about PTSD would be extremely relevant to both criminal and tort law, with a special focus on the latter.

In Criminal Law, improving PTSD assessment methods for victims of crimes (e.g. child abuse or sexual assault) would be important to determine civil compensations.

In Tort Law, neuroscientific techniques could be used to determine compensatory damages. This could lead to a re-evaluation of the distinction between physical and emotional harm. Emotional harm has been defined as including “distress [...] anxiety, diminished enjoyment, loss of autonomy, and similar intangible harms”. In Italy, a recent decision of the *Corte di Cassazione*¹ stated that the emotional (or non-monetary) harm (*danno non patrimoniale*) does include the award of compensatory damages when an unlawful act has seriously undermined a constitutionally protected right, even in absence of an express *ad hoc* rule providing for them. We believe that developments in neuroscientific research undermine the distinction between the two categories of harm, by showing that even stress disorders have a physical basis.

¹ *Corte di Cassazione* can be defined as an Italian Supreme Court. It is the most important civil and criminal jurisdiction. It interprets the law in controversial cases and formulates legal principles which lower courts will have to conform to.

In the last paragraph, the use of preventive drugs for people who have been exposed to traumatic events but have not developed symptoms yet is discussed. We discuss Kolber's (2006) and Henry's (2007) ethical and legal concerns about "memory dampening" and the freedom of memory, i.e. the right to choose to maximize mental welfare by attenuating memory².

2. The Origin of PTSD: A Brief History

PTSD has been surrounded by controversy much before its first appearance in the third edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-III) in 1980.

The alleged presence of the disorder in past centuries has been reported. The British Journal of Psychiatry, for instance, described how the *Diary of Samuel Pepys*³ delineated the syndrome as a consequence of the Great Fire of London in 1666, concluding that the features were correspondent to the ones in the DSM-III (Joung 1995)⁴. In the Nineteenth Century, the British physician John Erichsen firstly described the conditions of railways accidents' victims as "neurological mechanisms", calling them "railway spine" (Erichsen 1866)⁵. Before his description of psychiatric injuries, the term "trauma" was associated only to physical injuries. The scientific community soon began to show more interest for this new category. The French neurologist Jean-Martin Charcot studied how fear causes psychiatric symptoms in absence of any spiral injury or lesion. He distinguished this "new" neurosis from the so-called "hysteria" on the basis of etiology (fear) and called it "traumatic hysteria" (Libbrecht and Quackelbeen 1995)⁶. At the beginning of the 20th century, however, the idea of a purely emotional-based injury was still difficult to accept. In the opening lecture of the 43rd Annual Meeting of the Medical Society (1913), in California (USA), J.T. Fisher⁷ expressed doubts about a mental condition caused solely by trauma. He thought that, for "traumatic hysteria" to develop, some antecedent condition or congenital predisposition had to be present. Then he proposed a radical change in treatment. The "traumatic hysteria" patient should be kept at total rest, because:

² Kolber A.J. (2006), "Therapeutic Forgetting. The Legal and Ethical Implications of Memory Dampening", *Vanderbilt Law Rev.* 59(5), pp. 1561-1626.

Henry M., J.R. Fishman, S.J. Youngner (2007), "Propranolol and the Prevention of Post-Traumatic Stress Disorder: Is It Wrong to Erase the 'Sting' Of Bad Memories?", *American Journal of Bioethics*, 7(9), pp. 12-20.

³ The detailed private diary Pepys kept from 1660 until 1669 was first published in the 19th century. It provides a combination of personal revelation and eyewitness accounts of great events, such as the Great Plague of London, the Second Dutch War and the Great Fire of London.

⁴ Young A. (1995), "The Harmony of Illusions. Inventing Post-Traumatic Stress Disorder", Princeton University Press, Princeton (NJ).

⁵ Erichsen J.E. (1866), *On Railway and Other Injuries of the Nervous System*, Walton and Maberly, London.

⁶ Libbrecht K., J. Quackelbeen (1995), "On the Early History of Male Hysteria and Psychic Trauma. Charcot's Influence on Freudian Thought", *Journal of the History of the Behavioral Sciences*, 31(4), pp. 370-384.

⁷ James T. Fisher, M.D. and one of leading experts on hysteria in the first part of the 20th century.

If, after the accident, the patient is quietly isolated, removed from his friends and family, instructed that he must lie perfectly quiet and not converse, supplied with a nurse who can control her own mechanism of speech and under the medical care of a physician who understands the disease, we would hear very little of persisting traumatic hysteria. Instead of this he always gets sympathy, his complaints are received as though they represent real organic trouble and instead of rigid discipline, he is allowed to follow his sensations and nurse his disease; he becomes a chronic invalid. He is fed on indulgence and morbid suggestion which is the food which fattens the disease⁸.

Some commentators⁹ locate the first modern descriptions of PTSD in the period of the Russo-Japanese War (1904-1905), in which high-explosive shells were used for the first time. Contemporary reports recognized a condition amounting to a traumatic war neurosis, marked by confused states of mind, brief excitement and irritability, fearfulness, and emotional instability.

After the First World War other kinds of definitions were given to the anxiety and the stress presented by soldiers. The possibility that after a big trauma a person could have “lost his nerve” with strong physical and psychological consequences was not controversial anymore¹⁰. The birth of the current concept of PTSD is especially linked to the Vietnam War. In the 1970s some veteran groups extensively lobbied the DSM-III task force. Psychiatrist Chaim Shantan, who assisted the groups, coined the expression “post-Vietnam syndrome” as something new and different from previously described combat adjustment problems. These groups’ purpose was to draw national attention on the syndrome and to increase the chances for PTSD to be recognized as an independent disease. A first important achievement of the DSM-III was to create a diagnostic category to classify a chronic condition in previously healthy patients who developed long-term symptoms following an extremely traumatic event (war, rape, natural disaster)¹¹. Nevertheless, fourteen years later, DSM-IV changed the definition of traumatic exposure in this way: “the person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others,” and which evoked “intense fear, helplessness, or horror.” Further research had revealed that PTSD symptoms were more prevalent in the general population than was originally believed to be. Hence the criterion for a traumatic stressor was broadened in the 4th edition of the DSM¹². In general, the core features of PTSD in DSM IV-TR (2000) are:

⁸ Fisher J.T. (1913), “Traumatic Hysteria”, *Cal State J Med*, 11(10), pp. 414-415.

⁹ Merskey H., A. Piper (2007), “Posttraumatic Stress Disorder Is Overloaded”, *Can J Psychiatry*, 52, pp. 499-500.

¹⁰ Yehuda R., A.C. Mc Farlane (1995), “Conflict Between Current Knowledge About Posttraumatic Stress Disorder and Its Original Conceptual Basis”, *Am J Psych.*, 152, pp. 1705-1713.

¹¹ Yehuda, Mc Farlane (1995), “Conflict Between Current Knowledge About Posttraumatic Stress Disorder”, p. 1706.

¹² Criterion A: stressor: The person has been exposed to a traumatic event in which both of the following have been present: 1. The person has experienced, witnessed, or been confronted with an event or events that involve actual or threatened death or serious injury, or a threat to the physical integrity of oneself or others. 2. The person’s response involved intense fear, helplessness, or horror.

- a traumatic event that involved actual or threatened death or serious injury, or threat to the physical integrity of self and others, resulting in a person's responding with fear, feelings of helplessness, or horror;
- the re-experiencing of the trauma in nightmares, intrusive thoughts (flashbacks);
- the numbing of responsiveness, or avoidance of thoughts or acts related to the trauma;
- symptoms of dysphoria and hyperarousal.

The diagnosis of PTSD requires the persistence of symptoms for at least one month.

Accordingly to the last version of the DSM, therefore, the current method to assess PTSD is still behavioral.

The broadening of the PTSD definition in DSM IV has drawn criticism from Harvard psychologist R. McNally (2009)¹³. In his opinion the current diagnostic criteria are far too broad. The fact that it is sufficient to be "confronted with" an event that involves a threat to the physical integrity of others to satisfy criterion A1 makes most American TV viewers eligible for the label of "trauma victim". In particular, "horrified viewers of television coverage of the September 11, 2001 terrorist attacks" would satisfy both parts of criterion A and count as 'trauma survivors'. According to McNally this can also be a problem for the quest for a biomarker of PTSD. If trauma victims are so broadly defined, their neural states will be extremely diverse, so that it would become difficult to find consistent and recurring activation patterns in them. Therefore McNally proposes to eliminate informational exposure as qualifying as trauma. The proposal has of course momentous consequences for plaintiffs looking for compensation after having simply witnessed a traumatic event.

3. Neuroimaging and PTSD

3.1. *The State of the Art*

Neuroimaging is composed of three different techniques: functional Magnetic Resonance Imaging (fMRI), Positron Emission Tomography (PET), and Single Photon Emission Computed Tomography (SPECT)¹⁴. All of these techniques measure signals that have to do with variations in the regional Cerebral Brain Flow (rCBF). When a region of the brain is more active than a baseline, it consumes more energy and recruits more blood. These three techniques have respective advantages and drawbacks, which we will not examine here, and have been used to investigate PTSD.

Neuroimaging studies have examined PTSD using various paradigms, which can be grouped into three categories: symptom provocation paradigms, active task paradigms, and resting paradigms. In symptom provocation paradigms the patient receives stimuli that are connected with the trauma she experienced, in the attempt of eliciting the typical symptoms of PTSD. In active task paradigms the patient has to perform a

¹³ McNally R.J. (2009), "Can we Fix PTSD in DSM-V?", *Depress Anxiety*, 26, pp. 597-600.

¹⁴ Francati V. *et al.* (2007), "Functional Neuroimaging Studies in Posttraumatic Stress Disorder: Review of Current Methods and Findings", *Depress Anxiety*, 24, pp. 202-218.

task, such as matching emotion-expressing words with emotional facial expressions. In resting paradigms the subject remains in a base-line state – she normally fixates a white cross or dot on a black screen.

Given the diversity of the techniques and paradigms used in the neuroimaging of PTSD, together with the wide gamut of traumas which have caused PTSD in the examined subjects (veterans, rape victims, motor vehicle accident victims, and so on), it is not surprising that the results are highly variable. Nonetheless one experimental finding is quite consistent: The regional Cerebral Blood Flow (rCBF) in the Medial Prefrontal Cortex (MPFC) is lower in PTSD patients relative to healthy patients¹⁵. Another relatively consistent finding is the higher amygdala activation in PTSD patients relative to controls. According to Shih *et al.* (2004)¹⁶, the increased rCBF in the amygdala and the decreased rCBF in the MPFC positively correlate with the symptoms of PTSD. The bilateral amygdala is the principal structure that mediates fear in the human brain. It receives input from thalamic nuclei that lie on the main sensory pathways, so that it is rapidly informed of the presence of dangerous stimuli. Its relation with the MPFC and in particular with the Anterior Cingulate Cortex (ACC) is mainly of top-down inhibition: The ACC stops the fear response when the situation is no longer frightening, or simply when a sufficiently long time from the stimulus has passed. The main conclusion one could draw from these results is that PTSD is at least partially caused by a loss of regulation of the amygdala-MPFC system. Since fear contributes to create particularly resilient episodic memories, the excessive activity of the amygdala may lead to the hyper-consolidation of the traumatic memory and to the obtrusive flashbacks that beset the lives of those with PTSD.

However, these results must be considered with caution. Van Wingen *et al.* (2011)¹⁷ have found that the heightened amygdala response spotted in PTSD is not specific for this disease. The rCBF to the amygdala and the insula is regularly higher than usual when healthy subjects undergo severe and repeated stress. Even though this makes the activation of the amygdala a relatively unreliable biomarker for PTSD, this is compatible with a theory that sees PTSD patients as victims of a bad regulation of the fear response, since fear would make them experience continual stress.

3.2. Georgopoulos' MEG Experiments

The experiments recently carried out by the team of Apostolos Georgopoulos at the University of Minnesota are interesting for a variety of reasons. First of all, they make use of a relatively unexplored technique, MagnetoEncephalography (MEG). In the ex-

¹⁵ Liberzon I., C.S. Sripada (2008), "The Functional Neuroanatomy of PTSD: A Critical Review", *Progress in Brain Research*, 167, pp. 151-168.

¹⁶ Shin L.M. *et al.* (2004), "Regional Cerebral Blood Flow in the Amygdala and Medial Prefrontal Cortex During Traumatic Imagery in Male and Female Vietnam Veterans With PTSD", *Arch Gen Psychiatry*, 61, pp. 168-176.

¹⁷ Van Wingen G.A., E. Geuze, E. Vermetten, G. Fernández (2011), "Perceived Threat Predicts the Neural Sequelae of Combat Stress", *Molecular Psychiatry*, 16(6), pp. 664-671.

periments (Georgopoulos *et al.* 2010; Engdahl *et al.* 2010)¹⁸ PTSD-affected veterans and healthy subject were compared. Their cerebral magnetic fields were recorded while they were fixating a light dot. The MEG scanner was equipped with more than 200 gradiometers, i.e. sensors. The correlations between the signal records of couples of sensors were computed. In this way Synchronous Neural Interactions (SNI) were calculated. The method tries to uncover synchronization patterns across the cortex, examining how different neuronal ensembles modulate their activity during time and relative to other ensembles. SNI is not a new technique, since the same research group had published a paper in 2007 (Georgopoulos *et al.* 2007)¹⁹ in which they explained the method and claimed to be able to use it to find biomarkers of a long series of mental pathologies. Using a sophisticated statistical procedure, Georgopoulos and colleagues could create predictors that were able to classify PTSD-patients and healthy controls with a sensitivity of 97,3% and a specificity of 87,6%. A curious aspect of these experiments is that the difference in synchronous activation between healthy subjects and PTSD-affected veterans was localized in the right temporal cortex, an area of the brain that is not associated with PTSD according to current theories. Georgopoulos *et al.* suspect that the marker is connected with only one of the many symptoms of PTSD, namely “flashbacks”, the frequent re-experiencing of the traumatic memory. Even though the area is marginal relative to the general etiology of PTSD, the classifiers of Georgopoulos also allow to estimate the severity of PTSD.

The novelty of this result lies in the kind of experiment (a resting paradigm), in the high accuracy rate, and in the relatively high number of subjects involved.

Although this is a very promising result, the experiment has some limitations. The PTSD patients were all “pure” PTSD-patients (with PTSD only), and hence were not representative of the overall PTSD populations, as many PTSD-patients exhibit comorbidity. Furthermore, the study included war veterans only, so that at the moment results cannot be generalized to other PTSD-patients whose condition is not caused by participation in military action.

An objection that can be made against these experiments is that MEG is still a relatively experimental technique. This is true, but it does not impinge *per se* upon the value of the results, unless MEG is proven unreliable. Moreover, Williams and Sachdev (2010)²⁰ have recently argued that MEG can allow to classify Alzheimer’s disease patients relative to Mild Cognitive Impairment (MCI) patients, and could in the future help find biomarkers for Major Depressive Disorder and schizophrenia. Finally, Siek-

¹⁸ Georgopoulos A.P., H.R.M. Tan, S.M. Lewis, A.C. Leuthold, A.M. Winkowski, J.K. Lynch, B. Engdahl (2010), “The synchronous Neural Interactions Test as a Functional Neuromarker for Post-traumatic Stress Disorder (PTSD): A Robust Classification Method based on the Bootstrap”, *Journal of Neural Engineering*, 7, 016011.

Engdahl B., A.C. Leuthold, H.R.M. Tan, S.M. Lewis, A.M. Winkowski, T.N. Dikel, A.P. Georgopoulos (2010), “Post-traumatic Stress Disorder: A Right Temporal Lobe Syndrome?”, *Journal of Neural Engineering*, 7.

¹⁹ Georgopoulos A.P. *et al.* (2007), “Synchronous Neural Interactions Assessed by Magnetoencephalography: A Functional Biomarker for Brain Disorders”, *Journal of Neural Engineering*, 4, pp. 349-355.

²⁰ Williams M.A., P.S. Sachdev (2010), “Magnetoencephalography in Neuropsychiatry: Ready for Application?”, *Curr. Opin Psychiatry*, 23, pp. 273-277.

meier and Stufflebeam (2010)²¹ have shown in a review about MEG and schizophrenia that schizophrenic patients exhibit a distinguishable MEG pattern, constituted by increased theta (4-8 Hz) and delta (1-4 Hz) band oscillations in the temporal cortex.

We consider Georgopoulos' work as a first step towards a neuroscientific approach to the assessment of PTSD. New neuroscientific evidence is likely to complement soon the traditional behavioral strategy, without removing it. Of course many other studies are necessary to replicate Georgopoulos' results and to extend them to other populations, but the road is open to a broad neuroscientific investigation on the biomarkers of PTSD and other psychiatric ailments. Research will have to be methodologically sound in order to have a legal impact: the admission of scientific evidence into courts is subjected to strict conditions in most jurisdictions around the world.

In addition to meeting standards of scientific thoroughness, MEG-based psychiatric research will have to face the problem of the scarce diffusion of MEG scanners. These are as costly as MRI-scanners – their price in 2007 was about two million US dollars²² – but much less common. Nevertheless, if MEG evidence became admissible in courts, specialized firms that offer MEG to plaintiffs in PTSD compensation lawsuits would rapidly appear. The main concurrent of MEG, ElectroEncephaloGraphy (EEG), is far less expensive, as it requires no scanner at all, but just a set of electrodes. If biomarkers discovered by MEG could be found using EEG too, this new way of assessing PTSD and other psychiatric conditions would be able to spread at a much faster rate.

4. PTSD in Court

The assessment of PTSD in court has a great importance both in criminal and civil trials. In the former case, it could lead to the solution of a case. PTSD can be present only if a traumatic experience actually occurred. Given that this traumatic event is caused, in criminal trials, by a felony or a misdemeanor, the presence of PTSD can be considered as evidence that the criminal act has indeed occurred.²³

In the latter case the presence of a psychological trauma is crucial in order to recognize damages in tort claims. The broadening of the stressor criterion in DSM-IV has undoubtedly resulted in estimates of PTSD prevalence rates that are higher than the previous ones and in a surge of PTSD-based litigation in injury contexts.

New methods of assessment of this mental condition would be very relevant for the civil procedure, especially if those methods could lead to a re-definition of the adjective “psychological”, shifting toward a more “physical” consideration.

A brief analysis of the legal regulation of compensation of emotional injury within the Tort Law context is here proposed in a comparative way on civil-law and common-

²¹ Siekmeier P.J., S.M. Stufflebeam (2010), “Patterns of Spontaneous Magnetoencephalographic Activity in Patients with Schizophrenia”, *Journal of Clinical Neurophysiology*, 27(3), pp. 179-190.

²² Dottinga R. (2007), “MEG Scanners are Mega Powerful”, *Wired*, April 1, 2007, [online], URL: <<http://www.wired.com/medtech/health/news/2007/01/72277>> (last accessed: 28/05/2011).

²³ For the potential circularity of using a diagnosis of PTSD as evidence for the actual occurrence of the criminal act, see § 3.1 below.

law systems. Both in Civil-Law and Common-Law systems, two classes of damages can be awarded: pecuniary and non-pecuniary. The goal of pecuniary damages, that provide compensation for direct financial loss associated with the injury (e.g., medical expenses, future loss of earnings), is to return the injured party to their original, pre-injury position. The second class of damages, non-pecuniary damages, compensate for non-tangible losses such as pain, suffering, and loss of enjoyment of life.

PTSD is a particular psychiatric condition because it is defined by its cause: a traumatic event. As traumatic events are frequent, especially under the broader definition provided by DSM-IV-TR, it is not surprising that PTSD is becoming one of the most commonly litigated mental health conditions. Although the Courts have recognized the compensability of symptoms associated with PTSD, there appears to be a certain judicial reluctance to award compensation in such cases, especially in criminal cases²⁴. The main difficulty in these cases is represented by the tendency to ask the court to admit a diagnosis of PTSD as the evidence of an abuse, in order to prove the crime. There is indeed a clear problem of circularity, since clinicians cannot apply the PTSD diagnostic criteria without opining about the nature, extent and even existence of a reported stressor event.

In tort law cases, courts seems to admit PTSD with less resistance than in criminal trials. In the next paragraph we will now examine compensation for psychological harm in US, English and Italian tort law.

4.1. The Legal Framework

American Tort Law and Emotional Stress

In the middle of the 20th century the American Law Institute's 'Restatement of Torts' limited recovery to instances where the tortfeasor "subjects another to the mental suffering incident to serious threats to his physical well-being".

American Law deals with emotional harm in relation to four distinct torts:

- Assaults;
- Intentional infliction of emotional distress;
- Negligent infliction of emotional distress;
- Parasitic emotional harm, within the area of Damages²⁵.

Negligent Infliction of Emotional Distress and Parasitic Emotional Distress are particularly relevant for cases of PTSD.

²⁴ In US case law, for instance, see: *State v. Allewalt*, 517 A.2d 741 (Md. 1986); *Chapman v. State*, 18 P.3d 1164 (Wyo.2001).

²⁵ In the description of their main features, we make reference to the Restatements of Law, a series of legal treaties authored by the American Law Institute. They are commonly considered to offer guidance to courts in shaping the law. The Third Restatement has been recently drafted, but it refers only to product liability rules and commentaries. As to the tort law, the reference is going to be the Second Restatement of Torts and the draft of the Third Restatement, to be approved in 2011.

Only over the last 50 years, the former tort has been recognized by courts as an independent cause of action. It was previously considered as subjective, difficult to categorize, and possibly open to fraudulent harm. Concerns were expressed also with regard to the permission of legal redress for only temporary harm, the danger of falsification of the mental harm, and the perception of unfairness related to the assignment of damages to a negligent actor²⁶. The recognition of this category of tort is still controversial and two US states still do not recognize it.

Section 46 of the Restatement (Third) of Torts draws on judicially developed tests to limit recovery for emotional harm caused by a negligent actor to two situations. It provides that a person whose negligent conduct causes “serious emotional disturbance” to another is liable if the defendant’s negligence either a) places the plaintiff in “immediate danger of bodily harm,” or b) the negligence occurs in the context of special relationships in which negligent conduct is especially likely to cause serious emotional disturbance. These two situations are defined “as two lines of exceptions to the general rule that an actor is not liable for negligent conduct that causes only emotional harm”²⁷.

With regard to the Parasitic Emotional Distress, the US legal system considers it as the consequence of some negligently inflicted physical injury. Various expressions have been used to describe this damage category, such as “emotional damages” or “loss of enjoyment of life”. This kind of distress is recognized in all US jurisdictions, the only disagreement being about considering it a separate form of damages or an aspect of damages for pain and suffering²⁸.

English Law and Nervous Shock

In the English legal system, legal responsibility for psychiatric damage is an aspect of negligence liability: Patients to be compensated in a case of psychiatric injury must prove that the development of a psychiatric syndrome was someone’s fault. Three conditions of liability are required: (1) a duty of care owed by the defendant to the patient, (2) a breach of that duty, and (3) resulting damage. In order to receive compensation for negligently inflicted psychiatric illness, the plaintiff must take several steps to demonstrate these conditions²⁹. The most relevant is proving he is suffering from a “recognizable psychiatric illness” or, as called in English law, *nervous shock*. The requirement of “being recognizable” excludes from the definition of psychiatric illness emotions like anxiety, fear, grief, or transient shock. These emotions are not enough, even though there is no need to specifically prove the existence of PTSD.

²⁶ Kircher J.J. (2006), *The Four Faces of Tort Law: Liability for Emotional Harm*, Marquette University Law School Legal Studies, Research Paper Series, 06-43, <http://papers.ssm.com/sol3/papers.cfm?abstract_id=967539> (accessed 28/05/2011).

²⁷ Restatement (Third) sec. 46.

²⁸ Kircher J.J. (2007), *The Four Faces of Tort Law: Liability for Emotional Harm*, Marq. L. Rev., 789, pp. 798-806.

²⁹ Adamou M.C., A.S. Hale (2003), “PTSD and the Law of Psychiatric Injury in England and Wales: Finally Coming Closer?”, *J Am Acad Psychiatry Law*, 31(3), p. 328.

The present standards about liability for psychiatric illness, not resulting from plaintiff's physical injuries, are summarized in some decisions of the House of Lords: *McLoughlin v. O'Brian*³⁰, *Alcock v. Chief Constable of South Yorkshire Police*³¹, and *Hunter v. British Coal Corp*³².

In particular *Hunter v. British Coal Corp.* identifies three categories of primary victims: (1) those who were induced to fear physical injury to themselves; (2) those who came to the rescue of the injured; (3) those who believed that they were about to be, or had been, the involuntary cause of another's death or injury. A secondary victim must satisfy further requirements to succeed in a claim, such as: the nature of the relationship between the plaintiff and the primary victim; the proximity of the plaintiff to the accident or its immediate aftermath; the means by which the plaintiff perceived the events or received the information; and the manner in which the psychiatric illness was caused. Furthermore, the event must be one that is shocking to a person of normal fortitude.

Italian Law and "Danno Biologico"

In Italy the general rule in civil liability provides that the defendant can be held liable for damage when the existence of a link of causation between the action of the defendant and the harm can be proved. The onus of that proof generally lies with the petitioner.

A recent decision (2008) of the *Corte di Cassazione*³³ ruled about the relationship between pre-existent sub-categories within the non-pecuniary damage tort. On the basis of the previous interpretation of article 2059 of the Italian Civil Code, compensation for civil damages was awarded by the Italian courts under four different categories of loss:

1. *Danno biologico*: damages related to the harmed party's physical injuries or psychological condition, regardless of any loss of income. The court calculated damages using annually adjusted tables that base compensation levels on the claimant's age and the extent of their permanent disability.
2. *Danno morale soggettivo*: "moral damages" compensated a claimant for pain and suffering on an equitable basis. The amount of compensation varies according to the circumstances of the accident, the type of injury, and the extent of disability. Generally, moral damages will be calculated to be between $\frac{1}{4}$ and $\frac{1}{2}$ of the value of biological damages.
3. *Danno esistenziale*: "existential damages" compensate the claimant for the loss of a full quality of life. This compensation can take place regardless of the loss of income and without necessarily involving permanent physical injury. No medical assessment was required for this category of distress.

³⁰ *McLoughlin v. O'Brian* (1983) 1AC 410, 421-422.

³¹ *Alcock v. Chief Constable of South Yorkshire Police* (1991) 4 All ER 907 ss.

³² *Hunter v. British Coal Corp.* (1988) 2 All ER 97.

³³ *Corte di Cassazione*, SS.UU., November 11, 2008, n. 26972.

In the normal practice, every time a plaintiff suited an action to ask recovery for non-pecuniary damages, he had the chance to obtain a tripartite amount of money. Within the legal doctrine there was a sharp debate about possible (and concrete) abuses of these requests of money.

With the 2008 decision, the *Corte di Cassazione* reforms the tripartite category of non pecuniary damage. The Court states that the non-monetary harm (*danno non patrimoniale*) does include the award of compensatory damages when an unlawful act has seriously undermined a constitutionally protected right, even in absence of an express *ad hoc* rule providing for them. Thus, the subcategory of *danno esistenziale* is not necessary anymore.

A prominent role is now assigned to the *danno biologico*, to be intended as a damage to the individual's psychic and physical integrity, including the damage to the person's relational life. Both the moral harm and the changes in life that a person experiences as a consequence of an unlawful act is to be evaluated by the judge. He will consider the practical non-pecuniary harm, adjusting the amount of damages on each case.

4.2. PTSD and Pain: The Subjectivity of Perception

The question of whether PTSD is a physical or emotional injury, or both, comes up in various lawsuits. A few courts have acknowledged that PTSD, itself, can be a physical injury based on neurological changes associated with the disease³⁴. The District Court for the Eastern District of Arkansas (US), for instance, has stated that "PTSD is a biological/physical as well as a psychological injury"³⁵. In tort law several courts have considered the concept of "medical diagnosable" emotional injury as crucial. Many concerns, however, remains about malingered claims for psychological injuries.

The same concerns stemming from PTSD have been traditionally showed with regard to the legal assessment of pain and chronic pain. Lawyers for plaintiffs who suffer from chronic pain have implemented legal strategies to tackle the challenge of representing people who experience pain, when the basis for their pain experience cannot be proven by tests already considered objective such as x-ray scans. On an individual level, reaction to pain is conditioned also upon: (1) psychological and emotional factors; (2) demographic factors such as age, gender, cultural ethnicity, religion, and education; (3) physical factors such as activity level; (4) social factors such as employment status and litigation; and (5) elements of family history such as family behavioral patterns that rewarded or punished dependency and how one was taught to react to pain. For example, Harvard University anesthesiologist Henry K. Beecher noted in a 1956 article that soldiers who had been wounded in battle complained of much less pain than did patients with similar injuries in a civilian hospital³⁶. Beecher reasoned that, in the context

³⁴ *Ligeti v. British Airways*, No. 00-2936, 2001 WL 1356238, at *5 (S.D.N.Y. Nov. 5, 2001).

³⁵ *In re Air Crash At Little Rock, Arkansas*, On June 1, 1999, 118 F. Supp. 2d 916, 925 (E.D. Ark. 2000). The Arkansas District Court was reversed on that point by the Court of Appeals for the Eighth Circuit.

³⁶ Beecher H.K. (1956), "Relationship of Significance of Wound to Pain Experienced", *JAMA*, 161(17), pp. 1609-1613.

of having survived a battle, an injury has honorable connotations, possibly lessening the negative sensation.

Lawyers depend on the use of expert witnesses to demonstrate that their client is suffering from a serious condition or disability. The plaintiff's attorney must fight against subjectivity on two fronts: first in establishing that the expressed pain is tied to a palpable, present and embodied pain, and second in defining the contours, causation, and consequences of that pain. The law resolves the tension between subjectivity and objectivity by considering subjective clues of pain and suffering to the extent that they are not contradicted by objective evidence, and by crediting narrative constructions of pain to the extent that they do not conflict with medical evidence or other objective clues of disability³⁷.

Chronic pain and PTSD are undoubtedly correlated.

It often happens that people feel no pain immediately after a severe trauma. Nonetheless, if the acute stress persists and become chronic, pain usually intensifies, and bad mood or depression may increase that pain. Depression, which is frequently co-morbid with PTSD, may cause a person to avoid or limit physical activities, resulting in disability and poorer health which eventually increases the likelihood of pain. Many traumatic events may lead to the experience of pain and the more severe a traumatic event, the more likely it is that a person will experience some kind of physical injury as well as develop PTSD. Certain symptoms of PTSD may lead to the experience of pain. For example, hyper-arousal symptoms of PTSD may cause frequent muscle tension that could result in chronic pain.

4.3. Neuroscientific Evidence in Civil and Tort Law

The British Psychological Society's document *Psychologists as expert witnesses: Guidelines and procedures for England and Wales (2007)* defines an expert witness as

a person who through special training, study or experience, is able to furnish the Court, tribunal, or oral hearing with scientific or technical information which is likely to be outside the experience and knowledge of a judge, magistrate, or jury³⁸.

All legal systems have had to confront the increased complexity of the modern world. It has led to the increased use of experts in the courts of law. The BPS's definition is broad enough to delineate the essential features of an expert who is called to give his opinion both in civil-law and common-law systems. In common-law jurisdictions, such as in UK or US, the expert is most frequently instructed by the solicitor or the attorney, acting for either the prosecution or the defense, while in civil-law systems he is mostly court-appointed, especially in civil cases (even if the parties have the faculty to appoint

³⁷ Camporesi S., B. Bottalico (2011), "Can e finally 'see' pain? Brain imaging techniques and implications for the law", *Journal of Consciousness Studies* (forthcoming).

³⁸ Psychologists as Expert Witnesses: Guidelines and Procedures for England and Wales. Final Report August 2007, The British Psychological Society Expert Witness Working Party.

their own experts). In any case, the expert's evidence will be allowed only if it is deemed relevant and admissible, where relevance is determined by the probative value of the evidence in the particular case by the judge hearing the case. In both legal systems the judge is the ultimate gatekeeper of whether or not expert testimony is allowable³⁹.

It is likely that the finder of fact (judges and jury) will require input from a psychologist in order to assess the impact of a claimed PTSD, chronic pain, or other psycho-physiological disorder. The goal for the psychological expert confronting PTSD will be in this case to identify a given individual's area of dysfunction, determine whether and to what degree those dysfunctions relate to the traumatic event, and present the description in terms that are relevant to the court process.

Neuroscience tries to narrow the gap between physical and mental harm. If it succeeds, there will probably no justification for their different treatment anymore.

Especially within UK and US common-law systems, some scholars have examined promises and limits of this neuroscientific approach.

For instance, Grey (2007; 2011) highlights the following opportunities: (1) quantifying levels of distress experienced in response to certain stimuli and circumstances, (2) verifying claims for PTSD on the basis of neuroscientific tests, and (3) eliminating the so-called "arbitrary" tests for limiting emotional harm claims, i.e. physical impact, physical manifestation, and zone of danger⁴⁰. She maintains that we might "rethink our approach to the tort of emotional distress once we begin to document the physiological changes that occur in the brain from stress and fear". She also points out four main limits of the neuroscientific approach: (1) it is necessary to have some evidence of the plaintiff's condition prior to the accident, in order to exclude pre-existent conditions; (2) since all brain studies are based on averages, it is difficult to extrapolate neural correlation to prove injuries in individual cases. This also requires to determine the boundaries of the tort, that is defining the level of necessary correlation; (3) as it is unlikely that we would preclude current evidence to verify emotional harm, how will this evidence relate to brain scan evidence (as a prerequisite, superfluous or corroborative)? d) If some type of neuro-evidence is available, can the plaintiff be penalized for not proffering such evidence⁴¹?

Viens (2007) and Tovino (2007) agree that neuroscientific studies trying to identify neural correlates of emotional pain and distress might have effects on tort law⁴². Viens, however, emphasizes with skepticism the limits of functional neuroimaging technology

³⁹ In the US legal systems, the scientific evidence is admitted according to two main standards provided by the case-law: the Frye Test and, more recently, the Daubert Standard, currently the most applied in US Courts.

⁴⁰ Grey B. (2007), "Neuroscience, Emotional Harm, and Emotional Distress Tort Claims", *American Journal of Bioethics*, 7(9), pp. 65-67.

Grey B. (2011), "Neuroscience and Emotional Harm in Tort Law: Rethinking the American Approach to Free-Standing Emotional Distress Claims", *Current Legal Issues*, Oxford University Press, Oxford.

⁴¹ Grey (2011), "Neuroscience and Emotional Harm in Tort Law".

⁴² Viens A.M. (2007), "The Use of Functional Neuroimaging Technology in the Assessment of Loss and Damages in Tort Law", *Am. J. Bioethics*, 7(9), pp. 63-65.

Tovino S. (2007), "Functional Neuroimaging and the Law: Trends and Direction for Future Scholarship", *Am. J. Bioethics*, 7(9), pp. 44-56.

in determining non-economic and non-physical losses and damages. He shares Grey's concerns about the necessary comparison with neuroscientific data obtained before the injury, and about drawing a boundary line to define "how many brain states are sufficient to qualify as a loss for tort law?"

He also underlines that neuroscience might be helpful for establishing only certain elements of tort claims, since issues about actual breaches of duty will be a matter of fact for judges and juries to decide. Furthermore, not all psychological harms would be empirically verifiable. The proposed example is about the harm of indignity, whose truth does not depend on a person's specific mental states. We must avow that these last claims seem quite obvious to us. To our knowledge nobody has argued against these theses in the debate: nobody expects neuroscience to do all the work.

In our opinion the impact of neuroscientific methods to assess pain and symptoms related to the diagnosis of PTSD is still difficult to foresee with sufficient precision. We maintain, however, that neuroscience research will be able to undermine the distinction between current categories of harm, by showing that even stress disorders have a physical basis. The continual effort of neuroscientists to uncover biomarkers for chronic pain or for psychiatric ailments is likely to bring about this effect.

We share Grey's opinion about the possibility of rethinking our approach to the tort of emotional distress. Experiments such as Georgopoulos's show that over time we will be able to explain emotional suffering through the brain's structure and function in a more sophisticated way.

Moreover, we reply to some of the remarks above.

Firstly it is not true anymore that no brain studies can attain the individual level. Decoding techniques such as multivariate pattern analysis⁴³ allow to decode in fMRI Blood Oxygen Level Dependent (BOLD) activation patterns which are spread in the whole brain and to correlate them to some specific mental condition. For example, it is possible to understand, on the individual level, if a subject has added or subtracted two natural numbers that appear on a screen. The classifier must be previously trained with sure examples of addition and subtraction, but after that the algorithm can easily extract information from the BOLD pattern and identify what the subject has done on an individual basis. Therefore, neuroimaging can already go on the individual level, with the caveat that it is always necessary to train the classifier with some reliable cases of the mental state one wants to decode.

Secondly, as to the question about the role of neuroscientific evidence with respect to current evidence to verify emotional harm, we maintain that it will be mainly corroborative. Since there are still many subjective elements to be evaluated ("the subjective experience of pain"⁴⁴) and various components of the individual's life (such as age, job and so on), the assessment of the actual damage of a traumatic event will never be

⁴³ Haynes J.D., G. Rees (2006), "Decoding Mental States from Brain Activity in Humans", *Nature Reviews Neuroscience*, 7, pp. 523-534.

Haynes J.D., K. Sakai, G. Rees, S. Gilbert, C. Frith, R.E. Passingham (2007), "Reading Hidden Intentions in the Human Brain", *Current Biology*, 17, pp. 323-328.

⁴⁴ Kolber A. (2007), "Pain Detection and the Privacy of Subjective Experience", *American Journal of Law & Medicine (Brain Imaging & The Law Symposium)*, 33, p. 433 ss.

only physical. Legal evaluations have to consider the effect of an event on the person's life, and it is uncontroversial that the role of judges and juries will remain fundamental, as well as the contribution of other kind of evidence.

Thirdly, as to the problem of how many brain states are sufficient to qualify as a loss for tort law, we argue that it is not clear whether this is a real problem. Everything hinges on what kind of mental states one is assessing. In the case of chronic pain, for instance, it is theoretically possible that a single fMRI examination is sufficient. It would not be necessary to repeat the test various times, if we have no reasons to suppose that the condition of the plaintiff changes in time relative to the level of pain. If instead the plaintiff claims that her chronic pain waxes and wanes over time, multiple tests will be required.

Fourthly, at least for pain assessment, the problems of the baseline and of the exclusion of pre-existent conditions in fMRI are very serious. The former problem might be solved by training a classifier algorithm with a substantial number of ascertained chronic pain patients of the relevant kind (etiology, intensity, level of impairment) and healthy controls, whereas the latter seems to be hard to tackle in neuroscientific terms, since a neuroscientific test can tell us little about how a determined brain was in the past. Therefore conventional evidence, such as medical records or the testimony of the plaintiff's general practitioner will be required to exclude pre-existent conditions.

5. Conclusion

We have explored the relationships between neuroscience, PTSD, and law. Our main claims have been the following:

- neuroscience will provide courts with new tools to diagnose PTSD and to assess the presence of chronic pain;
- these techniques will produce new forms of evidence, but neuroscientific evidence is not likely to replace the old behavioral evidence;
- neuroscientific evidence may allow to bridge the gap between physical and emotional damage in PTSD and chronic pain compensation lawsuits;
- no sweeping legal prohibition against the use of propranolol in PTSD prevention ought to be passed, if the molecule is proven effective through clinical trials.

References

- Adamou M.C., A.S. Hale (2003). "PTSD and the Law of Psychiatric Injury in England and Wales: Finally Coming Closer?". *J Am Acad Psychiatry Law*, 31(3).
- Beecher H.K. (1956). "Relationship of Significance of Wound to Pain Experienced". *JAMA*, 161 (17).
- Camporesi S., B. Bottalico (2011). "Can we finally 'see' pain? Brain Imaging Techniques and Implications for the Law". *Journal of Consciousness Studies* (forthcoming).
- Dotinga, R. (2007). "MEG Scanners are Mega Powerful". *Wired*, April 1, 2007, [online] URL: <<http://www.wired.com/medtech/health/news/2007/01/72277>> (last accessed: 28/05/2011).
- Engdahl B., A.C. Leuthold, H.R.M. Tan, S.M. Lewis, A.M. Winkowski, T.N. Dikel, A.P. Georgopoulos (2010). "Post-traumatic Stress Disorder: A Right Temporal Lobe Syndrome?". *Journal of Neural Engineering*, 7.
- Erichsen J.E. (1866). *On Railway and Other Injuries of the Nervous System*. Walton and Maberly, London.
- Fisher J.T. (1913). "Traumatic Hysteria". *Cal State J Med*, 11(10).
- Francati V. et al. (2007). "Functional Neuroimaging Studies in Posttraumatic Stress Disorder: Review of Current Methods and Findings", *Depress Anxiety*, 24.
- Georgopoulos A.P. et al. (2007). "Synchronous Neural Interactions Assessed by Magnetoencephalography: A Functional Biomarker for Brain Disorders". *Journal of Neural Engineering*, 4.
- Georgopoulos A.P., H.R.M. Tan, S.M. Lewis, A.C. Leuthold, A.M. Winkowski, J.K. Lynch, B. Engdahl (2010). "The Synchronous Neural Interactions Test as a Functional Neuromarker for Post-traumatic Stress Disorder (PTSD): A Robust Classification Method Based on the Bootstrap". *Journal of Neural Engineering*, 7, 016011.
- Grey B. (2007). "Neuroscience, Emotional Harm, and Emotional Distress Tort Claims". *American Journal of Bioethics*, 7(9).
- Grey B. (2011). "Neuroscience and Emotional Harm in Tort Law: Rethinking the American Approach to Free-Standing Emotional Distress Claims". *Current Legal Issues*, Oxford University Press, Oxford.
- Haynes J.D., G. Rees (2006). "Decoding Mental States from Brain Activity in Humans". *Nature Reviews Neuroscience*, 7.
- Haynes J.D., K. Sakai, G. Rees, S. Gilbert, C. Frith, R.E. Passingham (2007). "Reading Hidden Intentions in the Human Brain". *Current Biology*, 17.
- Henry M., J.R. Fishman, S.J. Youngner (2007). "Propranolol and the Prevention of Post-Traumatic Stress Disorder: Is It Wrong to Erase the 'Sting' Of Bad Memories?". *American Journal of Bioethics*, 7(9).
- Kircher J.J. (2006). *The Four Faces of Tort Law: Liability for Emotional Harm*. Marquette University Law School Legal Studies, Research Paper Series, 06-43, [online], URL: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=967539> (accessed 28/05/2011).
- Kolber A. (2007). "Pain Detection and the Privacy of Subjective Experience". *American Journal of Law & Medicine (Brain Imaging & The Law Symposium)*, 33.

- Kolber A.J. (2006). "Therapeutic Forgetting. The Legal and Ethical Implications of Memory Dampening". *Vanderbilt Law Rev*, 59(5).
- Libbrecht K., J. Quackelbeen (1995). "On the Early History of Male Hysteria and Psychic Trauma. Charcot's Influence on Freudian Thought". *Journal of the History of the Behavioral Sciences*, 31(4).
- McNally R.J. (2009). "Can we Fix PTSD in DSM-V?". *Depress Anxiety*, 26.
- Merskey H., A. Piper (2007). "Posttraumatic Stress Disorder Is Overloaded". *Can J Psychiatry*, 52.
- Siekmeier P.J., S.M. Stufflebeam (2010). "Patterns of Spontaneous Magnetoencephalographic Activity in Patients with Schizophrenia". *Journal of Clinical Neurophysiology*, 27(3).
- Tovino S. (2007). "Functional Neuroimaging and the Law: Trends and Direction for Future Scholarship". *Am. J. Bioethics*, 7(9).
- Viens A.M. (2007). "The Use of Functional Neuroimaging Technology in the Assessment of Loss and Damages in Tort Law". *Am. J. Bioethics*, 7(9).
- Williams M.A., P.S. Sachdev (2010). "Magnetoencephalography in Neuropsychiatry: Ready for Application?". *Curr. Opin Psychiatry*, 23.
- Yehuda R., A.C. Mc Farlane (1995). "Conflict Between Current Knowledge About Posttraumatic Stress Disorder and Its Original Conceptual Basis". *Am J Psych.*, 152.
- Young A. (1995). "The Harmony of Illusions. Inventing Posttraumatic Stress Disorder". Princeton University Press, Princeton (NJ).

Biobanks between Law and Technology: How to Promote Data Sharing in the Digital Era

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Abstract: Modern concept of “open science” emphasizes the importance of data sharing, also favoured by the digitization of information. In biomedical research, the sharing of pre-competitive information and raw data is essential and biobanks are crucial to undertake it. The sharing of biobank data invests many legal areas: property on samples, privacy, contracts and intellectual property. Using a Law & Economics approach, this paper critically examines the challenges that biobanking raise to the legal regime of intellectual property and particularly to “diritto d’autore”/copyright on databases. After a comparative outline of the legal framework on the topic, the paper develops a perspective based on the analysis of four different models for the data sharing in biobanking (contracts, open source, open access and open access governance) in order to provide possible solutions.

Contents: 1. Introduction - 2. The Legal Protection of Databases: Stepping Stone or Stumbling Block? - 3. Old Fears and Modern Prometheus - 4. Models of Sharing - 4.1. Contractual Model - 4.2. Open Source Model - 4.3. Open Access Protocol - 4.4. Open Access Governance Model - 5. “Give Sharing a Chance”: The Potentiality of Research Biobanks - References

1. Introduction

Over the last decade, progress in science and technology has profoundly innovated traditional research methods. This transformation has become particularly evident in the biomedical sector, whose development, especially in oncology, has been propitiated by the advent of translational research. The latter is based on pre-clinical bio-molecular analysis of a critical mass of human biological samples in order to obtain results immediately usable in the clinical context. This permits the identification of biomarkers, i.e. those molecules that can predict the risk of cancer, the presence of a neoplasia and the possibility to identify the drug or the treatment most appropriate and effective for a particular patient. The progress in understanding the molecular mechanisms of genetic diseases and metabolic disorders and the impulse provided by pharmacogenomics make now real the promises of predictive and personalized medicine.

However, some recent studies have showed that despite growing public and private investments in drug discovery, the results are gradually reduced¹. At the origin of this phenomenon there are some factors as the insufficient scientific understanding of biological and molecular mechanisms of disease, the limited availability of data and biological samples, the lack of collaboration between researchers working in academia and industry, and the complex landscape of IPRs.

Data sharing and collaborative research have become an imperative in contemporary science, whose development depends inextricably on: the opportunities to access and use data, the possibility of confrontation between communities of practices, the cross-checking of information and results and, chiefly, on interactions with experts in other fields of knowledge. In this revolution, the key factor has been the digitization of information: it allows the sharing, modification and improvement and aggregation of data. Therefore, knowledge can circulate fast and can be implemented by the contribution of privates, companies and institutions.

Data sharing allows both to spread the costs of analytical results that researchers cannot achieve working individually and, if properly managed, to avoid the duplication of research. These advantages are critical in the biomedical field: without the sharing of already developed pre-competitive information and, above all, simple raw data, it is condemned to a dangerous stalemate.

This is why in the biomedical field new institutions such as research biobanks have gained in importance. Biobanks are powerful tools and organizational structures essential for translational research. They are a source of human biological samples stored in a biorepository according to high standards of quality and safety. Besides the material aspect, a biobank has also an informational content; in its databases are classified clinical/diagnostic information, sample-derived genetic data, donor's personal data, and the type of consent given for the research. Such data have a surplus value for translational research because they are constantly updated with donor's fol-

¹ Weigelt J. (2009), "The Case for Open Access Chemical Biology", *EMBO reports*, 10(9), p. 941; Booth B., R. Zimmel (2004), "Prospects for Productivity", *Nature Reviews Drug Discovery*, 3, p. 451; Cuatrecasas P. (2006), "Drug Discovery in Jeopardy", *J Clin Invest.*, 116, p. 2837.

low-up data: it is possible to follow the clinical history, the disease progression, the response to different therapies, etc.

Biobanks are at the centre of scientific debate because they raise a number of technological, ethical and social challenges. But they are also an exceptional case of “law and disorder”. There is no agreed definition of biobank (neither insider Europe!) and the jurist has to construct its legal framework from a Mosaic law. In fact, biobanks are right in the middle of the legal triangle IP-privacy-property: biological samples are subject of property rights; genetic sequence derived from the sample could be patented or covered by a trade secret; biobank’s database is under the protection of copyright or sui generis right; the handling of personal data, health records, genetic information must preserve the donor’s right of privacy.

Taking into account this many-sided panorama, the paper focuses on the challenges to widespread data sharing through biobanks. As I mentioned, the biorepository of a biobank stores a critical mass of samples; but how ever numerous they are, biological samples are still exhaustible resources. On the contrary, data are “ubiquitous”: they can be replicated n times and distributed to n researchers at the same time. So, access to biological samples is crucial but access to the data related with them is even more critical to the improvement of data sharing. Biobanks are the “treasure island” of pre-competitive information, crucial for basic research: it is important to provide a far-seeing legal regulation because they are the raw material for every research protocol in biomedical and pharmaceutical field. In order to think up new strategies, policies or structures to manage data, material and IPRs in biobanks, it is important to start analyzing the legal framework of database. Then I will examine both the models traditionally used for the exchange of material and information, and new fair access policies provided by technological revolution.

2. The Legal Protection of Databases: Stepping Stone or Stumbling Block?

The legal protection of databases was introduced by Directive 96/9/EC, which create a double track of protection². Besides the protection offered by copyright law (Chap. II), the Directive provides a “sui generis” protection for the maker of the database (Chap. III). This is an *unicum* at international level (for example, it is unknown in the U.S.) and is driven by the need to protect the investment of considerable human, technical

² Directive 96/9/EC of the European Parliament and of the Council on the legal protection of databases, in G.U.C.E., serie L, 27 marzo 1996, n. 77, p. 20. The directive has been transposed with d. Lgs. 6 maggio 1999, n. 169, amending the Italian Statute on copyright (L. 22 aprile 1941, n. 633/41). The directive defines the database as “a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means» (art.1). This protection is not applied to “computer programs used in the making or operation of databases accessible by electronic means”. The provision sprang from the exigence to avoid normative conflicts, in particular, with directive 91/250/EC on the legal protection of computer programs. Ronconi F. (2002), *Trapianto e rielaborazione del modello normativo statunitense: il diritto d'autore di fronte alla sfida digitale*, in Pascuzzi G., R. Caso (eds.) (2002), *I diritti sulle opere digitali*, Cedam, Padova.

and financial resources related to the collection of information that, mismatching with copyright requirements, would remain without any form of remuneration (whereas 7)³.

Copyright protects database which “by reason of the selection or arrangement of their contents, constitute the author’s own intellectual creation”, specifying that the protection is not extended to database content or the existing rights over it. So, copyright covers the expression of the database, the originality of its systematic organization. The intellectual contribution consists in the level of ease and efficiency with which the user’s access and the usability of content are drawn.

This goal is made possible by the deployment of forms of data, thesauri, indexing and cross-reference systems where the creativity of the author plays a key role⁴. Therefore, if the structure is original, with data organized in a creative manner – for example, not simply alphabetically or chronologically – the author of the database has the moral and economical rights⁵. The protection, as usually, lasts 70 years after author’s death.

Biobank has to be considered as a database: it is protected by copyright if its structure fulfils the criteria of selection and originality mentioned above. So, the way the samples are stored, linked together and accessible, on the basis of indexation system, has to be non obvious. The registers containing data may be copyrighted if it is not of routine nature (e.g. not structured in chronological or consecutive order). But also the coding/anonymizing system (a crucial element to ensure the donor’s privacy) should enhance its eligibility for copyright protection.

The *ratio* of the protection of the mere structure of the database lies on the traditional distinction between idea and expression. In our case, this implies that third parties are free to appropriate, using another form of expression, methods of organizing information, and reach – after an autonomous research on initial data – a result similar to that achieved by the original creator of the database⁶.

In order to counterbalance this “thin protection”, the Directive has provided a further right – so called “*sui generis*” – for the person which shows that there has been qualitatively and/or quantitatively a substantial investment to set up the database.

The right recognized by the directive to the maker of the database is significant. He can prevent extraction and/or re-utilization of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of that database (art. 7.1). So, the maker of the database can inhibit the permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form, such as the on-screen display of the contents (whereas 44). He may also transfer, assign or grant under contractual licence his *sui generis* right (art. 7.3).

³ There are similar form of protection in the English and Irish juridical system (doctrine of the “sweat of the brow”) and in Scandinavian countries (catalogue rule).

⁴ Imperiali R., R. Imperiali (2006), “La tutela giuridica delle banche dati”, *Diritto com. Scambi internaz.*, 2, pp. 377-384.

⁵ About the originality’s criteria in U.S.A. see the leading case *Feist Publications Inc. v. Rural Telephone Service Co.*, 499 U.S. 340 (1991). In that case was established that facts (an alphabetic list of a telephone directory) cannot be subject to copyright law.

⁶ Ronconi F. (2002), *Trapianto e rielaborazione del modello normativo statunitense* in Pascuzzi G., R. Caso (eds.) (2002), *I diritti sulle opere digitali*, Cedam, Padova.

This right has a hybrid nature: it does not coincide with the category of copyright, does not provide a moral right, is recognized also to companies and firms, does not require a minimum standard of creativity⁷. The only precondition is that «there has been qualitatively and/or quantitatively a substantial investment» (art. 7.1) and, as mentioned, such investment consists in the deployment of financial resources, the expending of time, effort and energy⁸. As for the term of protection, the sui generis right shall expire 15 years from 1st January following the date of completion or when the database was made available to the public for the first time (art. 10).

Relatively to lawful users, they must not perform acts which conflict with normal exploitation of the database or unreasonably prejudice the legitimate interests of the maker of the database, neither cause prejudice to the holder of a copyright or related right in respect of the works or subject matter contained in the database (art. 8.2-3). They can extract or re-use insubstantial parts of the contents of the database (art. 8.1), but not in a repeated and systematic way (art. 7.5). However, what does “an insubstantial part” mean? According to whom? Who decide the parameter? A set of data could be qualitatively substantial just because they are constantly updated: the only freedom accorded to users is nullified de facto because every extraction/use potentially affects a substantial part of the database. An interpretation by the ECJ is needed to establish the exact content of the term “substantial”.

The European dual system of database protection and, chiefly, the vagueness of sui generis right and its scope have raised some concerns from a legal point of view⁹. Academic community or other industries perceived it as locking up information; in the Italian transposition (art. 102-bis L. 633/41) the legitimate uses for educational or scientific purposes are not even considered. In addition, the 15-year exclusive right granted to the maker of the database looks like the monopoly granted to the patent, and it is much more pervasive: through the mechanism of substantial changes (art. 10.3), the power to inhibit the extraction or re-use can be extended without real time-limits¹⁰.

⁷ According to the European directive, the beneficiaries of protection under the sui generis right can be also companies and firms as long as “formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community; however, where such a company or firm has only its registered office in the territory of the Community, its operations must be genuinely linked on an ongoing basis with the economy of a Member State” (art. 11.2).

⁸ The ECJ intervened on November 2004, for the first time, establishing a distinction between creation of data and obtaining it. According to the Court: “the expression ‘investment in the obtaining of the contents’ of a database in Article 7(1) of Directive 96/9 on the legal protection of databases must be understood to refer to investment in the creation of that database. It thus refers to the resources used to seek out existing materials and collect them in the database but does not cover the resources used for the creation of materials which make up the contents of a database”. (Case C-46/02; C-203/02; C-338/02; C-444/02).

⁹ See: DG Internal Market and Services Working Paper, First evaluation of Directive 96/9/EC on the legal protection of databases, [online], URL: <http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf>. It is a right “under supervision”: every three years, the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on the application of the directive, in which, on the basis of specific information supplied by the Member States, it shall examine in particular the application of the sui generis right, and shall verify especially whether the application of this right has led to abuse of a dominant position or other interference with free competition which would justify appropriate measures being taken, including the establishment of non-voluntary licensing arrangements. Where necessary, it shall submit proposals for adjustment of this Directive in line with developments in the area of databases (art. 16).

¹⁰ Imperiali R., R. Imperiali (2006), “La tutela giuridica delle banche dati”, p. 393.

This possibility is made concrete by the use of technological protection measures (Article 102-quater L. 633/41).

The directive's aim was to stimulate the free movement of information, avoiding the establishment of monopolies on the raw data's sources or on the data itself. But the Community provision does not reach its goal: the sui generis right did not help to significantly improve the global competitiveness of the European database sector¹¹. Furthermore, this recent trend toward the appropriation of data is posing serious obstacles to full and open access to data for scientific purposes¹². Considering biobank as a public and independent infrastructure¹³, its institutional goal is to foster research, balancing the freedom of science/ist with the interest of participants and the public¹⁴. Biobanks' biorepositories and databases are a new example of "knowledge commons"¹⁵. Given that knowledge derives from information and information from data, biobank shall encourage the spread of knowledge through the free flow of data, a fair and equitable distribution of benefits from research using databases, and the reciprocity and exchange of information with fair return¹⁶. The biobank's dare is to keep the pathways to research open, but to make it possible it is necessary to consider (and to create the appropriate incentives for) the other player: the researcher.

3. Old Fears and Modern Prometheus

The language of sharing and the dialect of efficiency were not always spoken by scientists. The latter, probably for an ancestral instinct, have always tried to protect the results of their own "sweaty papers" with the most powerful tool to control knowledge: the secret¹⁷. As Paolo Rossi, philosopher and science historian, wrote

Communication and transmission of knowledge to be successful had to overcome many obstacles [...] but what we call 'communication of knowledge' (for us the current practice), has not always been perceived as a value. It has become a value. Communication as a value has always been contrasted with a different image of

¹¹ First evaluation of Directive 96/9/EC on the legal protection of databases.

¹² ICSU, Report of the CSPR Assessment Panel on Scientific Data and Information (2004).

¹³ Winickoff D., R. Winickoff (2003), "The Charitable Trust as a Model for Genomic Biobanks", *N Engl J Med*, 349, p. 1180.

¹⁴ OECD Guidelines on Human Biobanks and Genetic Research Database, [online], URL: <<http://www.oecd.org/dataoecd/41/47/44054609.pdf>>.

¹⁵ Hess C., E. Ostrom (2007), *Understanding Knowledge As a Commons*, MIT.

¹⁶ As established in HUGO Ethics Committee, Statement on Human Genomic Databases, 2002. See also, art. 18 of UNESCO's Universal Declaration on the Human Genome and Human Rights (1997) and artt.18-19 of International Declaration in Human Genetic Data (2003).

¹⁷ About the evolution from "secret science" to "open science" Caso R. (2008), *L'open access alle pubblicazioni scientifiche: una nuova speranza*, in Caso R. (ed.), *Pubblicazioni scientifiche, diritto d'autore e open access*, Atti del Convegno, Facoltà di Giurisprudenza, Università degli Studi di Trento, 20 giugno 2008, [online], URL: <<http://eprints.biblio.unitn.it/archive/00001589/>>.

knowledge: it has been conceived as an initiation, a secret, a heritage that few can draw, as a reality that must be disclosed to laymen with extreme caution¹⁸.

Open science, as part of public domain, it is a twentieth-century concept. The need to share results derives from the institutional goal of extending the boundaries of knowledge and it has been reinforced by the incentive of scientific publication¹⁹. This new awareness has been promoted, like modern Prometheus, by “revolutionary” researchers as Ilaria Capua. The Italian virologist identified the genetic sequence of the avian flu virus and decided to make it available to the worldwide scientific community uploading it to GenBank, disregarding the invitation of the WHO to file it in a limited-access database²⁰.

Nevertheless, this principle is struggling in biomedical research, where the secrecy used understandable concerns as a shield. It is easy to imagine that after working on a project for years, found the funds, obtained the necessary approvals by ethical and scientific committees, recruited participants, collected data and materials, carried out the tests, checked the technical quality and care of every single aspect, researchers might be reluctant to provide for free the fruit of their works. The prospect is even less attractive when we consider that other users would also be potential competitors, able to discover relationships that the researcher had not originally identified or invent something new from those studies. The researchers also fear to compromise their future ability to access research grants, which depend largely on the data sets that have been collected and increased over the years²¹.

Since it was found that data and materials are economically profitable discoveries, data sharing has become more complex. The transfer of information is not governed in a free and informal way according to the customary rules of the scientific community, because the gap between pure research and commercial application has gone thinning²². Data sharing does not arise spontaneously within the scientific community: we need to encourage it and provide incentives for collaboration to all stakeholders.

¹⁸ Rossi P. (1998), “La tecnica non ha morale, spetta agli uomini guidarla”, *Telèma*, 13, p. 65.

¹⁹ Merton R.K. (1973), *The Sociology of Science. Theoretical and Empirical Investigations*, Chicago-London, University of Chicago Press.

²⁰ Enserink M. (2006), “Italy’s Influenza Diva”, *Science*, November 10, 2006, pp. 918-919.

²¹ Gitter D. (2010), “The Challenges of Achieving Open Source Sharing of Biobank Data (April 30, 2010)”, *International Conference on Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology*, Department of Legal Sciences of the University of Trento, [online], available at SSRN, URL: <<http://ssrn.com/abstract=1598400>>.

²² Bennett A.B., W.D. Streitz, R.A. Gacel (2007), *Specific Issues with Material Transfer Agreements*, in Krattiger A., R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satynarayana, G.D. Graff, C. Fernandez, S.P. Kowalski (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, MIHR/PIPRA, p. 698.

4. Models of Sharing

Literature suggests four models for the exchange of data and materials in the context of biobank research:

- contractual;
- open source;
- open access;
- open access governance.

4.1. Contractual Model

The tools traditionally used for fruition of data and materials are respectively the Database License Agreement and the Material Transfer Agreement (MTA). The latter, in particular, is the current practice in the daily life of university and biobanks (the providers) in order to transfer for research purposes biological samples, software, chemicals, etc. to the recipients (another biobank, university or a private research centre)²³.

Contracts settle the parties' interests and express their autonomy. They are a flexible tools able to establish limits on the use of samples/data, resolve in advance any liability that might be derived from the use of samples/data, protect IPRs, etc.

But this model is really efficient to promote the sharing?

Some studies have shown that the MTA is cause of unrest among researchers²⁴. This feeling has been ironically described by Streitz and Bennett from UCLA's TTO:

One of your colleagues at BigAg, Inc. (or at BigAg University) says that she'd be happy to send you her transposon insertion lines that saturate the right arm of chromosome 9; you'll just need to have an MTA signed by your institution. Six months later, the terms of the agreement are still under negotiation, you've missed the field season, your grant has expired and there is now a better resource that's been developed at LittleAg University – and if you start negotiating an MTA now [...]. Welcome to the increasingly complicated world of sharing research materials –

²³ MTA is a hybrid: on the one hand, this tool determines the conditions under which the biological material, as tangible property, has to be transferred, on the other hand the same material can be subject of a patent application. MTA shall, in fact, consider and regulate the bundle of IPRs on the sample Bennett A.B., W.D. Streitz, R.A. Gacel (2007), "Specific Issues with Material Transfer Agreements", in Krattiger A., R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satynarayana, G.D. Graff, C. Fernandez, S.P. Kowalski (eds.) (2007), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Oxford, UK, MIHR/PIPRA, p. 698. On this topic, see also Margoni T. (forthcoming), *The Roles of Material Transfer Agreements in Genetics Databases and Bio-banks*.

²⁴ The negotiation of a MTA is often imposed by university administrators in order to protect their intellectual property rights or to prevent litigation. Lei, Z., R. Juneja, B.D. Wright (2009), "Patents versus Patenting: Implications of Intellectual Property Protection for Biological Research", *Nature Biotechnology*, 27(1), p. 36; Noonan K. (2009), "Conflating MTAs and Patents", *Nature Biotechnology*, 27, p. 504; Lei Z., B. Wright (2009), "Reply to Conflating MTAs and Patents", *Nature Biotechnology*, 27, p. 505; Ku K. (2007), "Point: MTAs are the Bane of our Existence!", *Nature Biotechnology*, 25, p. 721; Rodriguez V. (2008), "Governance of Material Transfer Agreements", *Technology in Society*, 30, p. 122.

those biological materials or reagents that are often essential, or at least helpful, to accelerate your own research²⁵.

For some authors, the length of the procedure is due to the slowness and the complexity of the academic mechanisms; for others the problem lies in the limitations of liability, in the long time that the negotiation of intellectual property rights requires, or in the lack of cooperation with industry (that rarely gives its results). The international doctrine unanimously attributes to MTA a dramatic slowness which hinders the timing of research and is not appropriate to the needs of science. On the contrary, some of the universities that have not adopted this model have seen significant losses²⁶.

To overcome these deficits has intervened Science Commons²⁷. This initiative, using the Creative Commons open licenses (CC) created contractual models for the transfer of research materials. In fact, the Biological Material Transfer Agreement Project has developed a standard MTA, flexible and modular, to solve the problem of high transaction costs in the transfer of biological material for research purposes. It is an easy instrument because its language “speaks” simultaneously to three different parties: the researcher (through the commons deed), the lawyer (through the legal code), and the machine (with the html).

The MTA, in fact, has an interface understandable even for scientific operators (non-lawyers); yet the computer code links the terms of the contract to the materials, in order to facilitate traceability. That contract is not monolithic as other “standard form” because it offers, through simple and user-friendly screens, some options to attach to the document. Without doubt, it is an interesting initiative: it creates a participatory tool, web based, easily accessible and intuitive, useful for the spread of biotech knowledge minimizing the transaction costs.

However, this model has the usual disadvantages of standardization and its modularity partially alleviates the problem by providing a space for autonomy (but it is limited only to certain aspects considered more important to adjust). The standardization helps to reduce transaction costs and to facilitate the circulation, but it creates difficulties in the field of open licenses. Again, the contract is always insufficient on the democratic and participatory aspects, because the contents of the agreement do not result from a negotiation, but it is unilaterally imposed²⁸. In addition, this model does not still satisfy – either settle – the point of the promotion of data sharing.

²⁵ Streitz W., A. Bennett (2003), “Material Transfer Agreements: A University Perspective”, *Plant Physiology*, 133, p. 10.

²⁶ Henderson J. (2007), “Counterpoint: MTAs are a practical necessity”, *Nature Biotechnology*, 25, p. 722.

²⁷ Science Commons is an initiative coming from Creative Commons (CC), since 2005. Using the CC licenses, the commons deed (the license’s summary) and metadata (license’s digital version), Science Commons aims to extend in the most appropriated way the philosophy and the structures of CC to the world of science: so, it provides contractual models for the transfer of research materials or the creation of open source platform in order to spread the knowledge and the visualization of data. The scope is to furnish easy tool both from the legal and technical point of view to promote scientific progress and research. Wilbanks J., J. Boyle, *An introduction to Science Commons*, [online], URL: <http://sciencecommons.org/wp-content/uploads/ScienceCommons_Concept_Paper.pdf>.

²⁸ On the problems related to the standardization of contracts: Roppo E. (1975), *Contratti standard: autonomia e controlli nella disciplina delle attività negoziali di impresa*, Giuffrè, Milano; Alpa G., M.

4.2. Open Source Model

The open source is a revolutionary and provocative concept, developed since the early '70s as part of computer science, and it represents a new way of thinking about computer programming and software in its entirety: from conception to the final release and the distribution. In addition to the binary code, the source code is also distributed to the public of user-programmers. In this way they cannot only use the software, but copy, modify and redistribute it²⁹. Free software is distinguished by a special legal regime that allows progressive development. According to the General Public License manifesto, it gives to the users the four “fundamental freedoms”: 0) run the program, for any purpose; 1) study how the program works, and change it to make it do what you wish; 2) redistribute copies; 3) distribute copies of your modified versions to others. The idea of Richard Stallman, founder of this movement, circumnavigates the temptation of any user of GPL licensed software to distribute the modified software with a proprietary license.

In the field of biomedicine, the open source philosophy is transformed into the “open source biotechnology” or “open science”³⁰. Here, the licensees cannot appropriate the fundamental “kernel” of the technology and improvements exclusively for themselves³¹: data and results of research should fall into the public domain (PD), but only under certain conditions, for example, by waiving an “unfair” use of IPRs. The participants, therefore, would agree to grant licenses or to exercise their rights in order to make available inventions and improvements to the whole community³². In this scenario, the patent holder should license the invention with a “viral license” that protects those technical solutions and improvements from possible attempts of appropriation, for example by commercial competitors. That has already been done by the BIOS’s CAMBIA, an Australian nonprofit research institute that has extended this model to the transfer of biological samples³³. Users of the BIOS ‘concordance’ do not assert IP rights against each other’s use of the technology to do research, or to develop products either for profit or for public good. Consequently, the improvements must be shared according to a BIOS license, while the products and inventions developed from the same technology can be patented. In the latter case, however, the improvements that have been patented must return (grant back clause) to the BIOS and to other licensees on the same terms of the original license.

Bessone (1997), *Il contratto standard nel diritto interno e comunitario*, a c. di F. Toriello, Giappichelli, Torino; Boggiano A. (1991), *International standard contracts: the price of fairness*, Graham & Trotman, Dordrecht.

²⁹ The idea of Free Software is linked to one name: Richard Stallman. In 1993 he set up the GNU project. It was an operative system compatible with Unix, a proprietary software. Stallman’s novel idea consisted in the creation of a license (copyleft, “all rights reversed”) giving much more power to the user than to the owner. About the origins of open source movement see Stallman R. (2004), *Software Libero Pensiero Libero*, Nuovi Equilibri, Viterbo.

³⁰ Gitter D.M. (2010), “The Challenges of Achieving Open Source Sharing of Biobank Data”, *Biotechnology Law Report*, 29, pp. 623-635.

³¹ See: BIOS concordance.

³² About the adoption of open source model in the biotech field, Hope J. (2008), *Biobazaar: The Open Source Revolution and Biotechnology*, Harvard University Press, London.

³³ [Online], URL: <<http://www.bios.net/daisy/bios/home.html>>.

However, the adoption of this approach does not dissolve some key issues such as private sector involvement, the property rights on materials and data and the benefit for participants. In addition, this model seems to ignore the exorbitant costs of intellectual property (e.g. the cost of patent application), and innovation in the biomedical field³⁴. The adoption of open source in biotechnology would, therefore, a high risk of rejection. Open source is a culture of sharing developed in the hacker community with needs different from the biotech world. Pharmaceutical companies want to get patents and license them as much as possible, while the researchers want to have credit and reputation for their works³⁵.

Furthermore, if getting the copyright is free and confers the right on the creation throughout the life of the author plus fifty or seventy years, we cannot say the same for patent: developing a new drug or a new diagnostic method requires time, money, infrastructure, highly skilled researchers and must comply with current legislation, which in most cases is a significant item of expenditure. Open source, therefore, may not provide the right incentives for effective collaborative research.

4.3. Open Access Protocol

Also open access (OA) has been translated in the field of biotechnology and, in particular, in bio-chemistry. OA is free online access. That means the freedom to access data without most of copyright and licensing restrictions³⁶. An initiative launched in 2008 by the Zurich Center for Integrative Medical Research and the Institute of Molecular Medicine of Zurich has tried to implement this model. The SciClyc (<<http://www.sciclyc.com>>) is an online database of biological materials which enables accredited researchers to collect and share data, publications, cell cultures, biopsies, reagents, software, antibodies, etc. and is, therefore, an open-access platform for the organization, management and the sharing of research materials which is based on collaboration through user-defined mobile devices.

Also Science Commons intend to procure a protocol for the circulation of scientific data³⁷. Moving from the awareness of the need of data's interoperability, the OA database protocol aims to provide the legal functions necessary to create a legal tool, in order to create a legally integration of different databases or data products³⁸. The key principles at the base of the initiative are the promotion of legal predictability and certainty, the user-friendly approach and the reduction of transaction costs. The protocol

³⁴ Gold R. (2010), "Models for Sharing Data", *Biobank Lab*, Università di Trento, May 13, 2010.

³⁵ Gold R. (2010), "Beyond Open Source: Patents, Biobanks and Sharing, International Conference Comparative Issues in the Governance of Research Biobanks", *Biobank Lab*, Università di Trento, May 13, 2010.

³⁶ Suber P., *Open Access Overview*, [online], URL: <<http://www.earlham.edu/~peters/fos/overview.htm>>.

³⁷ [Online]. URL: <<http://sciencecommons.org/projects/publishing/open-access-data-protocol/>>.

³⁸ At first, Science Commons encouraged the database licensing under the CC licenses or the GNU Free Documentation License. The initial approach was abandoned for 3 main reasons (category errors, false expectations, attribution staking) and now the scope is to converge on public domain.

suggests to converge on PD by: giving up IP, deleting the contract control, simplifying the citation requirements.

A similar approach would have the undeniable advantage to minimize transaction costs, allow sufficient flexibility and aggregation of data. However, these protocols should not lay down policies for the patentability of an invention obtained from that data and do not seem to offer clear incentives.

4.4. Open-Access Governance Model

Starting from the studies of Chesbrough³⁹, Weigelt and Edwards have applied the concept of “open innovation” to drug discovery, identifying as the best conditions for its development both the osmosis between private and public sector, and the adoption of open access structures⁴⁰. This strategy, called “open access governance”⁴¹, relies on OA protocols but, in addition, is based on governance structures and legal instruments.

The strength of an OA biobank, in fact, would not derive just from the exploitation of intellectual property rights, but from contracts and social norms, such as those typical of the scientific community. The open access governance model arises in the context of bio-chemical research. In this sector is crucial to have free access to the so called “chemical probes”, sophisticated chemical compounds created in laboratories by highly skilled staff, enabling the researcher to simulate in vitro the interactions of a single protein in a broader biological context (cells or organisms). Around these reagents, it has been created a vicious circle: the industries depend on universities to discover and validate new targets, but this validation is carried out only through the chemical probes, made by industry.

This new type of partnership between public and private sector (PPP) was adopted by the Structural Genomics Consortium (SGC), a non-profit organization founded in 2004 with the aim of promoting the development of new drugs, investing in basic research and releasing to the public every type of information (from reagents to know-how)⁴². The SGC’s primary goal is to determine the three dimensional structure of proteins, in order to understand the molecular mechanisms of their biological function. Then, the data obtained are deposited in the Protein Data Bank (PDB), a freely accessible archive, which since 1971 collects information about 3D structures of large molecules, including proteins and nucleic acids⁴³. This organizational model guarantees to the funders the right to indicate their priorities in the Target List, to appoint a

³⁹ Chesbrough H. (2003), *Open Innovation: The New Imperative for Creating and Profiting from Technology*, Harvard Business School Press, Boston.

⁴⁰ Weigelt J. (2009), “The Case for Open-access Chemical Biology”, *EMBO reports*, 10(9), p. 941; Edwards A.M., C. Bountra, D.J. Kerr, T.M. Willson (2009), “Open Access Chemical and Clinical Probes to Support Drug Discovery”, *5 Nature Chemical Biology*, 7, p. 436.

⁴¹ Gold R. (2010), “Beyond Open Source: Patents, Biobanks and Sharing, International Conference Comparative Issues in the Governance of Research Biobanks”, in *Atti del Convegno “Comparative Issues in the Governance of Research Biobanks”*, (Trento, 7-8 maggio 2010). [Online] URL: <<http://events.unitn.it/en/biobanks/program>>.

⁴² [Online], URL: <<http://www.thesgc.org/>>.

⁴³ [Online], URL: <<http://www.pdb.org/pdb/home/home.do>>.

member of the Scientific Committee and of the Board of Directors and to assume researchers in laboratories SGC with confidentiality agreements. But the consortium does not offer any precedence in access to data, research or its results.

The salient feature of the SGC policy implies that consortium and its researchers must release their products (materials and know-how) in the PD without posing any kind of restriction. As a result, the SGC and its employees refrain from seeking patent protection on any pre-competitive results (Figure 1).

This statement is expressed in a number of operational rules such as the refusal to enter into research projects in which is possible to obtain patents that may restrict or prevent subsequent research (competitive research), the waiver to be named as inventor and, if named, to make the patent available free of charge to all, the release of output data through free and publicly accessible digital repositories whilst complying with any applicable regulation including privacy.

5. “Give Sharing a Chance”: The Potentiality of Research Biobanks

The analyzed models are interesting solutions but, of course, there is no single answer to all dilemmas. What is sure is that pre-competitive information represents the first rung of the ladder of knowledge. If the access is off limits, it is impossible to climb and to progress in research. Biobanks are the steward of a critical mass of material and information, fundamental for biomedicine, that have to be used in a far-seeing and efficient way (to avoid the tragedy of commons and anticommens!). They have the institutional scope to foster research, managing:

- a. the biorepository, distributing samples, quantitatively and qualitatively significant, to researchers;
- b. digital databases, removing/reducing the risk of the underuse of scientific information.

In biobanking, the sharing requires a set of minimum conditions such as the universal access to large scale of data and materials for any research purpose, the possibility to conduct research and improve on materials, the chance to develop inventions, the sharing of the possible improvements or inventions, and the cost containment⁴⁴.

In this context, OA has to be balanced with the rights and the needs of all stakeholders, and the biobank governance can address the most pressing concerns such as the protection of donor/patient’s privacy (granting the anonymization or codification of materials), the respect of his own autonomy (registering the type and the range of informed consent given for the research), the guarantee of data confidentiality, and the ethical review of the research protocols (through the Institutional Review Board). The access should be granted, after an online registration, to all bona fide researchers applying for the material and informational resources. Furthermore, it is crucial not locking industry or for-profit organizations out. As the OA governance model suggested, it is

⁴⁴ [Online], URL: <<http://www.pdb.org/pdb/home/home.do>>.

important to catalyze the industry efforts, managing them in efficient and equitable ways throughout governance mechanisms and agreed policies.

Biobanks should gain the awareness of their value, in order to build a “research commons” through fair access⁴⁵. They represent an invaluable resource for science, so their role cannot be reduced to a “golden mine”. In my vision, biobank is an interactive resource in which each user can add something new and enrich the system. The researcher should grant back the results of his analysis (other pre-competitive information) to the biobank and share them with the scientific community. He should return the complete analysis (in order to permit the scientific review process) but, especially, the “blind alley”, that is the negative findings that can orient next developments and efforts. It is not an utopistic scenario: that is what already happen in O+ehun, the network biobank of Basque Country, that “oblige” researchers to submit periodical report on their results. The key point is the trust among researchers because they are part of the same network: they use the samples and data collected by their colleagues and they want to grow a common resource in the interest of the local research community. Such approach should be applied on a larger scale. Furthermore, feeding the findings back reduces the risk of research’s duplication. This provision also reflects the principles of altruism and reciprocity, that ideally should underlie scientific research.

A policy on data return could be propitiated not just with a license’s clause but through the most immediate incentive for a “collaborative researcher”: the visibility. It could be auspicious a feedback mechanism to reward the most zealous researchers, increasing his reputation in the “ecosystem of knowledge”. The same incentive is valid for the biobank. Anne Cambon-Thomsen has proposed the creation of a BIF (*Biobank Impact Factor*), a sort of *citation impact factor for biobanks*⁴⁶. The tool should quantify the biobank’s use, view the number of access, calculate the range and the impact of the research obtained, giving credit to those who created and maintained a valid resource. An high number of citation means research funds both for the biobank, the laboratory and the research group.

A grant back clause could discourage researchers, interesting in publication, from participation. In order to address this problem, the NIH grants a period of exclusivity for the data producer. In fact, the Policy for Sharing of Data Obtained in NIH Supported or Conducted GWAS Studies declares that investigators who contribute data to a NIH GWAS data repository retain exclusive right to publish analyses of dataset for maximum of twelve months following its release via the NIH GWAS data repository. During this period of exclusivity, NIH grants data access through Data Access Committees (DAC) to other investigators, who may analyze the data, but are expected not to submit their analyses or conclusions for publication until expiration of exclusivity period⁴⁷.

⁴⁵ Paraphrasing Suber P. (2007), *Creating an Intellectual Commons through Open Access*, in Hess C., E. Ostrom (eds.), *Understanding Knowledge As a Commons: From theory to practice*, MIT Press, Cambridge Massachusetts., p. 171.

⁴⁶ Cambon-Thomsen A. (2003), “Assessing the Impact of Biobanks”, *Nature Genet.*, 34, pp. 25-26.

⁴⁷ NIH Public Access Policies, [online], URL: <<http://publicaccess.nih.gov/>>.

In conclusion, it is necessary to look with interest to this novel solutions proposed for research biobanks. The experience in the biomedical field suggests to search for a middle position between IPRs and PD. In fact, a strong IPRs exploitation affects the freedom of science, the progress of knowledge and the work of the researchers. But also the PD does not provide appropriate incentives for scientists, industries and, paradoxically, for the general public. The recent trends presented in this paper demonstrate how it is possible to combine governance and property structures in order to establish a new balance in the research activity.

In this sense, biobank should store its own raw data but also the pre-competitive information granted back by bona fide researchers and, in turn, share them. As has been demonstrated, this sort of data should be freely accessible in research community for ethical and economics reasons.

In fact, because of high costs and the risk of duplication of research, it is inexpensive to share this basic information with competitors rather than obtaining them from scratch⁴⁸. Providing such data, biobank could give those tools able to accelerate the preclinical validation of the target and to prevent the wasteful phenomenon of the duplication of research. So, biobank will have the potentiality to foster research, innovation and technology transfer, acting as a connector between university, research centers, public and private corporations. It will be a modern “cornucopia”.

⁴⁸ Barnes M.R., L. Harland, S.M. Foord, M.D. Hall, I. Dix, S. Thomas, B.I. Williams-Jones, C.R. Brouwer (2009), “Lowering Industry Firewalls: Pre-competitive Informatics Initiatives in Drug Discovery”, *Nature Rev. Drug Discovery*, 8, p. 701.

References

- Barnes M.R., L. Harland, S.M. Foord, M. Hall, I. Dix, S. Thomas, I. Williams-Jones Bryn, R. Brouwer Cory (2009). “Lowering Industry Firewalls: Pre Competitive Informatics Initiatives in Drug Discovery”. *Nature Rev. Drug Discovery*, 8.
- Bennett A.B., W.D. Streitz, R.A. Gacel (2007). “Specific Issues with Material Transfer Agreements”, in Krattiger, A., R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, r. Sa t. Kanika, G.T. Graff, C. Fernandez, S.P. Kowalski (eds.). *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR, Davis / PIPRA, Oxford.
- Booth B., R. Zimmel (2004). “Prospects for Productivity”. *Nature Reviews Drug Discovery*, 3.
- Cambon-Thomsen A. (2003). “Assessing the Impact of Biobanks”. *Nature Genetics*, 34.
- Chesbrough H. (2003). *Open Innovation: The New Imperative for Creating and Profiting from Technology*. Harvard Business School Press, Boston.
- Cuatrecasas P. (2006). “Drug Discovery in Jeopardy”. *J Clin Invest.*, 116.
- De Robbio A., A. Corradi (2010). “Biobanche in bilico tra proprietà privata e beni comuni: brevetti o open data sharing?”. *JLIS.it.*, 1.
- Edwards A.M., C. Bountra, D.J. Kerr, T.M. Willson (2009). “Open Access Chemical and Clinical Probes to Support Drug Discovery”. *Nature Chemical Biology*, 5.
- Enserink M. (2006). “Italy’s Influenza Diva”. *Science*, 314.
- Gitter D. (2010). “The Challenges of Achieving Open Source Sharing of Biobank Data (April 30, 2010)”. *International Conference on Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology*. Department of Legal Sciences of the University of Trento, [online], URL: < <http://ssrn.com/abstract=1598400>>.
- Henderson J. (2007). “Counterpoint: MTAs Are a Practical Necessity”. *Nature Biotechnology*, 25.
- Hess C., E. Ostrom (eds.) (2007). *Understanding Knowledge As a Commons*. MIT.
- Hope J. (2008). *Biobazaar: The Open Source Revolution and Biotechnology*. Harvard University Press, London.
- Imperiali R., R. Imperiali (2006). “La tutela giuridica delle banche dati”. *Diritto commerciale e Scambi internazionali*, 2.
- Kaye J., M. Stranger (eds.) (2009). *Principle and Practice in Biobank Governance*. Ashgate, Farnham.
- Ku K. (2007). “Point: MTAs are the Bane of our Existence!”. *Nature Biotechnology*, 25.
- Lei Z., R. Juneja, B.D. Wright (2009). “Patents versus Patenting: Implications of Intellectual Property Protection for Biological Research”. *Nature Biotechnology*, 27.
- Lei Z., B.D. Wright (2009). “Reply to Conflating MTAs and Patents”. *Nature Biotechnology*, 27.
- Macilotti M., U. Izzo, G. Pascuzzi, M. Barbareschi (2008). “La disciplina giuridica delle biobanche (The Legal Aspect of Biobanks)”. *Pathologica*, 100, pp. 102-115.
- Margoni T., *The Roles of Material Transfer Agreements in Genetics Databases and Biobanks*. Forthcoming.

- Merton, R.K. (1973). *The Sociology of Science. Theoretical and Empirical Investigations*, University of Chicago Press, Chicago.
- Milanovic F., D. Pontille, A. Cambon-Thomsen (2007). “Biobanking and Data Sharing: A Plurality of Exchange Regimes”. *Genomics, Society and Policy*, 3.
- Noonan K.E. (2009). “Conflating MTAs and patents”. *Nature Biotechnology*, 27.
- Pascuzzi G. (2010). *Il diritto dell'era digitale*. Il Mulino, Bologna.
- Pascuzzi G., R. Caso (2002). *I diritti sulle opere digitali*. Cedam, Padova.
- Rodriguez V. (2008). “Governance of Material Transfer Agreements”. *Technology in Society*, 30.
- Ronconi F. (2002). *Trapianto e rielaborazione del modello normativo statunitense: il diritto d'autore di fronte alla sfida digitale*, in Pascuzzi G., R. Caso (eds.) (2002). *I diritti sulle opere digitali*, Cedam, Padova.
- Roppo E. (1975). *Contratti standard: autonomia e controlli nella disciplina delle attività negoziali di impresa*. Giuffrè, Milano.
- Rossi P. (1998). “La tecnica non ha morale, spetta agli uomini guidarla”. *Telèma*, 13.
- Simon B.M. “How to Get a Fair Share: IP Policies for Publicly Supported Biobanks”. *Stanford Journal of Law, Science & Policy*, Forthcoming.
- Stallman R.(2004). *Software Libero Pensiero Libero*. Nuovi Equilibri, Viterbo.
- Streitz W., A. Bennett (2003). “Material Transfer Agreements: A University Perspective”. *Plant Physiology*, 133.
- Suber P. *Open Access Overview*, [online], URL: <<http://www.earlham.edu/~peters/fos/overview.htm>>.
- Weigelt J. (2009). “The Case for Open-access Chemical Biology”. *EMBO reports*, 10.
- Wilbanks J., J. Boyle. *An introduction to Science Commons*, [online], URL: <http://sciencecommons.org/wpcontent/uploads/ScienceCommons_Concept_Paper.pdf>.
- Winickoff D.E., R.N. Winickoff (2003). “The Charitable Trust as a Model for Genomic Biobanks”. *N Engl J Med*, 349.

Genetic Tests “Direct-to-Consumer”: From “Informed Consent” to “Informed Will”

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Abstract: In the framework of *multilevel constitutionalism*, this paper analyzes the legal implications in the rise of *direct-to-consumer* genetic test market, with an aim to understanding if the regulation of genetic tests fits the new services. In order to uphold *privacy* as a right to informational self-determination, this paper intends to disprove the idea that genetic tests must always be proposed by a physician for diagnostic protocols or medical treatments. *Vice versa*, *privacy* implies the right to know our own genome, even for non-medical reason, despite the risk of health problems related to predictions of a genetic disease. The paper also surveys the relationship between privacy, freedom of science and the consumer’s possibility to file his genome in a biobank in order to obtain discounts on tests and/or determine the research field for his data.

Contents: 1. Genetic Tests “Direct-to-Consumer” and the “Heterogenie der Zwecke” of Genomics - 2. Genetic Tests and the Physician-Patient Relation - 3. Right of Access to Genetic Data, from “Informed Consent” to “Informed Will” - 4. Genetic Tests Consumers, Biobanks, Scientific Research 5. The Interference between Bills of Rights - References

1. Genetic Tests “Direct-to-Consumer” and the “Heterogenie der Zwecke” of Genomics

In recent years, several companies have been proposing the opportunity to apply for relatively low-cost genetic tests, using all the comforts of *via* internet communication.

Genetic tests can be purchased from the web page of the company, which will home deliver a vessel to be filled with a biological sample and sent back to the laboratory where tests will be performed. In two months the customer will be able to view the results of the genome scanning directly at home, by accessing to the laboratory's database using an ID and a password, and will even have the possibility to share that information by social-networking devices¹.

An international free market of genetic tests raised, in which the test is not necessarily a sanitary service related to a specific medical condition detected by a physician. Therefore, the test isn't necessarily integrated in a specific diagnostic protocol, or even taken under a medical treatment context. The test has become a simple device to acquire personal information, despite its original aims. It's not for nothing that the companies offering *DTC* genetic tests use particularly aggressive market strategies, in which they explain that the results can be useful to “shed light on your ancestors, your close family and, most of all, yourself”, to understand which diet or lifestyle fix better with yourself, to know your body reaction to nicotine assumption, or just to get “information to be shared for fun with family and friends”, as part of a new “recreational genomics”².

This element of innovation requires to answer the question about the persistent validity of actual genetic tests law³.

The regulation of genetic tests has been planned and developed in relation to a medical-diagnostic context, whether not even strictly therapeutic.

For example, in Italian law, we can recall the “Autorizzazione generale al trattamento dei dati genetici del Garante per la protezione dei dati personali del 22 febbraio 2007”⁴.

The Authorization, first written regulation which gave a complete identification of the genetic data in Italy, defines the “*genetic data*” as “the data which [...] concerns the genotype of an individual, or the genetic characters which are heritable between a group bounded by kinship” and distinguishes between a diagnostic test, which is intended to “perform a diagnosis or confirm a clinical suspect in a sick person”; a pre-symptomatic test, which is intended to “detect or discard the possibility of a genetic mutation related to a genetic disease which can arise in a healthy individual”, the predictive test, by which it is possible to “estimate the susceptibility of an individual for *the arise of a common disease*”. The Authorization provides a definition even for the

¹ Kaye J. (2008), “The Regulation of Direct-to-Consumer Genetic Tests”, *Hum Mol Genet*, 17(R2): R180-R183 [cited as in U.S. National Library of Medicine – National Institutes of Health OPAC Pubmed, <<http://www.ncbi.nlm.nih.gov/pubmed>>].

² Kaye J. (2008), “The Regulation of Direct-to-Consumer Genetic Tests”.

³ This paper focuses on the Italian context. However, also American Food and Drug Administration is facing the problem: in March 2011 FDA organized a meeting “focused specifically on issues regarding clinical genetic tests that are marketed directly to consumers where a consumer can order tests and receive test results without the involvement of a clinician”, (<<http://www.fda.gov>>).

⁴ “General Authorization for the submission of genetic”, given by the Italian privacy Authority on February, 22, 2007, G.U. n. 65, March 19, 2007.

pharmacogenetic test, which is intended to “detect a DNA sequence which can predict «individual» response to certain drugs”.

According to the Authorization, only healthcare professionals can collect genetic data and only for healthcare or for scientific research in medical field. The only exception is related to a medical-legal purpose: it is possible to collect genetic data for criminal trials, or for family reunification proceeding, in order to determinate family connections between the people concerned.

In this context, genetic tests regulation has been provided using the development of the law in the fields of privacy and of right to health.

Since the genetic information are personal data, their survey and circulation has been limited within specific cautions in order to avoid new discriminations and to safeguard the privacy of the interested person. This way, the main problem is given by two specific qualities of genetic data: “non-changeability” and “multiple-ownership”. It is well known that genetic data don’t change during a life-time, so it is absurd to think about the right to rectify the data against the database controller. It is also well known that genetic data not only refer to the person who submitted the test, but to a group of people bounded by kinship.

Moreover, by being the genetic analysis an health service, its development has been submitted to the “good medical practices”, in order to regulate the organization of medical centers, the physician’s liability and, above all, the patient’s right to give the “informed consent” before getting tested.

In Italy, the *Guidelines for genomics*⁵ provide rules for genetic laboratories (§ 5), in which privacy protection is the first aim. We can see that in § 7.2:

Informed consent for genetic test is the result of a procedure intended to help the interested person to decide to accept or not the test [...] the interested person receives all the needed information about test’s results and its consequences [...] the interested person is not urged into taking a certain decision [about accepting the test].

The concurrent use of rules regarding privacy for genetic data circulation and informed consent before a performing of the test has already shown itself as only partially suitable with genomics, even before the outcome of *DTC* genetic tests.

Genetic tests, as mentioned above, are used in the so-called *predictive medicine*, the branch of medical science that exploits the possibilities offered by the knowledge of human genome to foresee the risk of future phenotypic manifestation of a disease.

The exploitation of these potentials led to the emersion of the so-called “unpatients”: healthy people whose genotype shows predispositions to well known specific gene-related diseases⁶. By analyzing the human genome, it is possible to deduce the future onset of a genetically predetermined disease or, although with a non-irrelevant

⁵ “Linee guida per l’attività di genetica medica”, agreement between Italian Government and the Regions of Italy (Accordo in sede di Conferenza Stato-Regioni), dated July 15, 2004, G.U. September 23th, 2004, n. 224.

⁶ Jonsen A.R., S.J. Durfy, W. Burke, A.G. Motusky (2006), “The Advent of the “Unpatients”, *Nat Med*, Jun, 2(6), p. 622-624 [cit. Pubmed].

probabilistic factor, the risk of onset of a genetic proneness disease and the risk-factor to contract certain common diseases⁷.

First-type pathologies' onset is exclusively occasioned by a genetic mutation, as in Huntington's Chorea. Second-type pathologies are occasioned by the interaction between a pathological gene and the environment, as in Parkinson Disease. For this reason they are also called “multi-factorial” and “polygenic diseases”. Lastly, medical science has already ascertained that genetic condition – besides environmental and behavioral causes, contributes to determine the risk of onset of some complex – but common – diseases, as diabetes, heart diseases, schizophrenia and cancer.

Used for a predictive purpose, genetic tests exceed from diagnostic-therapeutic purpose and approaches a dimension in which the medical function – even the preventive one – became less and less important, up to disappear completely, to make room for the consciousness of information relevant for individual choices.

In case of predetermined genetic diseases, whose onset is sure in an uncertain time, the genetic analysis, that is completely bodily-harmless, carries an actual informative risk, depending on the psychological damage that the results of the tests may cause, especially when there is no possible recovery. Because of this, the results have a lot of psychological, social and reproductive implications. It has been noted that the reaction to an unfavorable test result is unpredictable and can cause a depressive syndrome or lead to equally harmful super compensating behavior, as in case of hyperactivity in sports, in an attempt to (demonstrate of being able to) keep our own life under control.

These elements led to the so-called “right not to know”, intended as every person's right not to be informed about the results of his genetic tests and their consequences, nor even about the results of the scientific research that may have used such data. This right is nowadays officially recognized, besides other international acts, by art. 10 of the *Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine (Oviedo Convention)*⁸.

The considerations above also concern the genetic proneness diseases and the common diseases related to a genetic factor. In these cases the relation – disproportionately high – between diagnostic instruments and therapeutic possibilities is even more complicated, since the test prediction and the ability to reduce the disease-risk are submitted to an unpredictable element which makes those information hardly useful to therapeutic or preventive aims. Studies about BRCA1 and BRCA2 genes, related to breast cancer in women, have been illuminating, because they highlighted the fact that there is no correspondence between the probability to develop a disease and an ade-

⁷ Garofalo L., V. Mele (2001), “Approccio bioetico e biogiuridico”, *Medicina e morale*, 1, p. 41; Bucci L.M., M. Raganella, A. Ventura, F. Ventura, R. Celesti (2005), “Osservazioni etiche e implicazioni medico-legali in materia di ‘test genetici’”, *Medicina e morale*, 4, p. 800. Research on the relation between the gene pool and the onset of common disease use the so-called genome-wide association studies (G.W.A.S.). In those researches, the whole genome of a number of individuals with a common character – being affected by a certain disease, having freckles – is studied to detect relations between a gene mutation and the incurrence of the character. “Wellcome Trust Case Control Consortium, Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls”, *Nature*, 2007, 447(7145), pp. 661-678 [cit. Pubmed].

⁸ The ratification of the Oviedo Convention has been authorized by Italian Parliament (legge n. 145 del 2001), but the ratification hasn't been yet registered.

quate prophylaxis to avoid that event, so that the interested person risks to suffer a severe upset without any advantage. Even in this case the therapeutical and medical aim goes fading, while the acquisition of relevant information for one's own life becomes predominant, in order to make choices about family, career, medical insurance, etc.

Informative aim becomes completely predominant on the medical one if we consider the case of pre-natal tests or hereditary/genetic-diseases detection tests, performed when both of the future-parents are carriers, f.i. with the thalassemia. In those situations, genetic tests do not affect the clinical condition of the people who applied for or demanded the test, because the results will affect the procreation choices by giving information about the condition of the embryo or of the offspring⁹.

So, we can assume that the "right not to know" has got an extra-medical *ratio*, intended not only to prevent psychological damages, but also, and above all, to safeguard the possibility to make personal choices. Moreover, knowing genetic data is always both related to healthcare and informative self-determination, taken here as the possibility to acquire personal data which will be used at complete discretion of the person they refer.

Therefore we can agree with those who underlines that the knowledge of genetic data has no necessarily therapeutic implications¹⁰, and most of all with those who ascertained that

in the field of genomics the informed consent shows peculiarities not experienced in the standard clinic field. We are suggested to sort out from this ambit, by knowing that dealing with genomics means facing new kinds of professional relations instead of the ordinary diagnostic-therapeutic situation¹¹.

2. Genetic Tests and the Physician-Patient Relation

To deal with genetic tests DTC we have to overcome the *informed consent* pattern in the relation between patient and physician. What options do we have?

One possibility is to introduce a general obstacle to apply for genetic tests and to bring back the use of genetic analysis in an exclusively medical treatment context¹². This opinion is based first of all on the genetic test qualification as a medical treatment – "genetic tests are the most important medical application of genetic research": *Guidelines for genomics*, art. 1, paragraph 3 – that can be performed only by individuals provided with a specific expertise, such as every diagnostic protocol, from a simple radiography to a more complex laparotomy. Moreover, only a physician or a geneticist can

⁹ On prohibition of pre-natal diagnosis ex art. 13, comma 3, lett. b), of legge n. 40 del 2004, cfr. Agosta S. (2005), *Tra ragionevoli preoccupazioni di tutela ed irragionevoli soluzioni normative*, in D'Aloia A. (ed.), *Bio-tecnologie e valori costituzionali*, Giappichelli, Torino, p. 105 ss. e 130 ss.

¹⁰ Garofalo L., V. Mele (2001), p. 46.

¹¹ Casini M., C. Sarteà (2009), "La consulenza genetica in Italia", *Medicina e morale*, 6, p. 1124.

¹² Bucci L.M. *et al.* (2005), p. 802. These authors report that many physicians don't agree with the use of genetic test in the diagnostic routine. This is because knowing about the risk of a disease's onset carries a harmful consequence: the risk of a gene-based discrimination. Therefore "we can see the professional opinion intended to stop, slop down or even abolish these diagnostic techniques".

provide a proper genetic counseling, taken here not only as the activity of reporting genetic-test results in a proper way, but even as the basic reading and decoding of genetic data to produce a useful medical report.

Furthermore, moving from the standings about the psychological risk due to the knowing of genetic-tests results and the social risk due to genetic-based discrimination, it could be possible to allow only a physician to prescribe the test. In this case, a person can apply for a genetic test only with a (medical) prescription.

It is possible to interpret this way both Italian and international genetic-tests law.

The already mentioned *2007 Authorization*, Art. 3, paragraph 1, specifically authorizes the use of the genetic data for healthcare purposes, with a particular mention for genetic pathologies, and for scientific-statistic research in medical field. The Authorization has a main purpose: healthcare. As limited exceptions, it contemplates the purposes of conscious procreation, already mentioned medical-legal aims¹³ and work health and safety, and it certainly lacks that freedom-of-use of genetic tests that can lead, as already told, to the so-called *recreational genomic*.

The *Oviedo Convention*¹⁴ appears to be even more pressing this way: in Art. 12 is ordered that

Il ne pourra être procédé à des tests prédictifs de maladies génétiques ou permettant soit d'identifier le sujet comme porteur d'un gène responsable d'une maladie soit de détecter une prédisposition ou une susceptibilité génétique à une maladie qu'à des fins médicales ou de recherche médicale, et sous réserve d'un conseil génétique approprié¹⁵.

The clinical-therapeutical purpose is confirmed (since the epigraph) by the *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes*, made in Strasbourg on November 27th, 2008¹⁶. In Art. 6 is well established that “Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons”, while art. 7 decides that

1. A genetic test for health purposes may only be performed under individualised medical supervision. 2. Exceptions [...] may not be made with regard to genetic

¹³ Genetic tests with a medical-legal purpose would remain available only to get information to identify a single human being or to prove the kinship relation between two individuals. No healthcare-related information would be obtained with those particular tests.

¹⁴ As already said, the Convention hasn't been ratified yet, therefore it isn't in force in Italy. At the most it can be used by courts only as an instrument “to detect a cultural background and to foresee a possible evolution of a legal system” [Luciani M. (2009), *Positività, metapositività e parapositività dei diritti fondamentali*, in Brunelli G., A. Pugiotto, P. Veronesi (eds.), *Scritti in onore di Lorenza Carlassare*, III, Jovene, Napoli, p. 1068 ss.].

¹⁵ Cited Art. 12 isn't inconsistent with Art. 10, comma 2, of the Convention, by which every person has the right to know his personal healthcare related data already collected (Toute personne a le droit de connaître toute information recueillie sur sa santé. Cependant, la volonté d'une personne de ne pas être informée doit être respectée). This is because art. 10, comma 2, is about already available data, but it doesn't say anything about the right to create and collect personal data with a genetic test on our own person, applying for a genetic test.

¹⁶ The protocol is open to the signature by member states. Italian Government hasn't signed it yet <<http://www.coe.int>>.

tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.

Same intentions in Art. 5 of the *International Declaration on Human Genetic Data*, given by UNESCO General Assembly:

Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of: (i) diagnosis and health care, including screening and predictive testing; (ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as «medical and scientific research»; (iii) forensic medicine [...].

The mentioned documents, even in a not so definite way, seem to propose a genetic data management system based on a relational model in which the physician's intermediation for every application for a genetic test is necessary, except for a few medical-legal cases, and the physician's autonomy in prescribing the test is ineradicable.

The fundamentals of this system, given as a possible interpretation of the documents examined before, can be summed as follows.

1. Genetic test can be performed only for healthcare, except for the medical-legal reasons already mentioned. The physician is the only one who can verify the existence of a healthcare purpose, therefore only the physician's will can lead the patient to get tested. After evaluating the clinical conditions of the patient, the physician can propose a genetic test, but only if it seems to be useful within a valid protocol to diagnose, treat or prevent a disease. For the predictive medicine, genetic test is considered a valid instrument only if other factors (such as the family medical history) indicate an actual disease-risk.
2. Proposal and consequent prescription of a genetic test is justified only if the genetic information will consent to react in a useful way for the health of the tested person, for instance when it's possible to submit the patient to an examination to get a diagnosis of a curable disease. On the contrary, genetic analysis is not justified where there is no possible recovery or treatment, nor experimental, not even partially effective, to the diagnosis that can be obtained from the test.
3. A physician should not prescribe a useless genetic test. Therefore he could abstain from prescribing pre-natal tests, out of conscientious objection, if the future mother's procreative choice could turn into the termination of pregnancy or, in case of assisted reproduction treatment, into the refusal of embryo implant¹⁷.

¹⁷ Casini M., Sarte C. (2009), p. 1133, uphold this hypothesis. Although, we can agree with the opposite theory, provided by Rodotà S. (1991), "Privacy e costruzione della sfera privata, ipotesi e prospettive", *Pol. del dir.*, 4, p. 537. For this author the objection to a pre-natal test is merely ideological.

4. Otherwise, if a genetic test seems to be useful because of an available therapy or prophylaxis, the patient still has the right to oppose to the analysis, that cannot be performed, as any other medical treatment, without his informed consent.
5. The patient keeps the *right not to know* even if he had already given the consent to the test: genetic data are a tool in the hand of the physician, who will consider them while formulating his therapeutic or prophylactic precept. Just in case, the patient could only know the genetic data which are very necessary to give informed consent to other treatment.
6. The circulation of medical data collected with a genetic test is only allowed with patient's consent, with an exception for the case in which the test reveals that a relative of the patient is in a clear, present and avoidable danger. In this circumstance the physician, considering every specific caution, can communicate the data to the interested person, in order to prescribe the proper remedies.
7. Given the “multi-ownership” of genetic data, the circulation of genetic information must not jeopardize the privacy of those people to who the information acquired by the test refers to.

The physician-patient relational model mentioned above gives a very little space to the DTC genetic test, that could be performed without the intermediation of a physician. Informed consent is still necessary to perform genetic analysis, but it comes after the previous evaluation of the physician, whose assent is necessary to access to genetic data. It is an evaluation that the specialist performs autonomously, far from that *therapeutic alliance* born with the informed consent.

Considered this, the overcoming of the informed consent, led to a model we can call “conditioned consent”, conditioned by the physician's evaluations, according to good medical practices provided by the Italian law and supranational law and by the professional code of conducts for medical ethics.

3. Right of Access to Genetic Data, from “Informed Consent” to “Informed Will”

Is the *conditioned consent* model compatible with the Italian Constitution or with E.U. law? There are good reasons to question about.

First of all, we have to underline the exceptionality of genetic data, characterized by their predictive ability, immutability and “multi-ownership”, has been put in doubt. In particular, it has been underlined that also some environmental and epidemiological factors, such as radiation exposure and HIV infection, are predictive and can determine the patient's clinical state in a irreversible way and give significant information not only for the person they refer to, but also for a larger community. Otherwise also fingerprints, the tone of voice and the retina characteristics are able to identify a person unequivocally. Most of all, it has been banally underlined that each medical check-up is able to provide unexpected information and to have unexpected impact on human exis-

tence. For these reasons, the genetic information should be considered similar to other medical data and should be handled the same way¹⁸, that is by safeguarding each person's right to know and to understand his own state of health, with free access to these significant data.

But the fact that it could be not completely possible to know personal data about our own person, about our own body – given that genetic information tells us *what* we are but not *who* we are, as rightly affirm those who contest the validity of the so-called genetic reductionism¹⁹ –, about the “hardest part of the «core» of privacy”²⁰ is in deep contradiction with the informative self-determination of every human being.

It has been said that the latest normative and cultural tendencies about privacy led to the acknowledgement of the *fundamental right* to informative self-determination, which should be included into human rights *ex art. 2* of the Italian Constitution. Right to informative self-determination is seen as “the right to keep control on every information which is relevant for a person, even when it is in the hands of other people”²¹. A right which represents the evolution of the original idea of privacy, that “has shifted aims and structure, underlining the element of the free individual choices, widening privacy borders until comprehending every rule about circulation of personal data, strengthening the constitutional significance of right to privacy”, therefore allowing the shift “from privacy to the right to informational self-determination [...], from data secrecy to data control”²².

Even without postulating the existence of a specific constitutional right, but simply realizing, as it has been said, that the informative self-determination represents a *value* that the legislator has to consider while regulating access and circulation of personal data²³, the right of access to one's own genetic data is protected by the E.U. directive October 24th, 1995, n. 95/46/CE.

The acknowledgement of the right of access is considered in the directive preamble: “any person must be able to exercise the right of access to data relating to him which are being processed” (remark n. 41); “Member States shall guarantee every data subject the right to obtain from the controller: [...] communication to him in an

¹⁸ Gainotti S., A.G. Spagnolo (2004), “Test genetici, a che punto siamo in Europa?”, *Medicina e morale*, 4, p. 750.

¹⁹ Modenesi C. (2006), *Dal riduzionismo della natura, alla natura del riduzionismo*, in Modenesi C., S. Masini, I. Verga (eds.), *Il gene invadente*, Baldini Castoldi Dalai, Milano, p. 30 ss.

²⁰ This is the definition of genetic data provided by Rodotà S. (1991), p. 539.

²¹ Rodotà S. (1991), p. 525 ss., spec. 540-543.

²² Rodotà S. (1997), “Persona, riservatezza, identità”, *Riv. crit. dir. priv.*, 4, p. 588 ss. About informative self-determination in German law see Ehmann H. (1998), “I principi del diritto tedesco in materia di trattamento dei dati personali con riguardo alla direttiva comunitaria del 24 ottobre 1995”, *Contratto e impresa in Europa*, 2, p. 898 ss. This author describes the Bundesverfassungsgericht's statement December 15th, 1983, which led to the Grundrecht auf informationelle Selbstbestimmung, BVerfGE, vol. 65, p. 43.

²³ That's the opinion of Pace A. (2006), *Art. 21. La libertà di manifestazione del proprio pensiero*, in *Commentario della Costituzione*, in Branca G. (ed.), Zanichelli-II Foro italiano, Bologna-Roma, p. 165. For this author we can surely see the informative self-determination as a constitutional right in German law, where it was developed originally, and in Spanish law. On the contrary, we could not detect such a constitutional right from Art. 2 of Italian Constitution. Therefore, in Italian law informative self-determination can be intended as a value, not as a constitutional right which can be taken in front of a court.

intelligible form of the data undergoing processing and of any available information as to their (Art. 12, comma 1, lett. a).

According to the case law of the European Court of Justice, the right of access is particularly significant, since it is a tool for the exercise of every right related to one's own personal data (right of rectification or erasure, right to give prior consent for data use and circulation, etc.)²⁴.

It is true that

Member States may, in the interest of the data subject or so as to protect the rights and freedoms of others, restrict rights of access and information; [...] they may, for example, specify that access to medical data may be obtained only through a health professional (remark n. 42)

and that

Member States may adopt legislative measures to restrict the scope of the obligations and rights provided for in Articles [...] 12 [...] when such a restriction constitutes a necessary measure to safeguard: [...] the protection of the data subject or of the rights and freedoms of others (Art. 13, comma 1, lett. g)

but this limitation cannot entitle the physician to be the one and only who can choose whether a person should know his genetic data.

With that interpretation of the directive, we would have a paternalistic concept of the relation physician-patient, which is inadmissible according to a constitutional set which grants the freedom of choice, even in front of the physician's therapeutic indications (Art. 32, paragraph 2, Cost.). In that case we would have a paradoxical effect: starting from the fact that a physician needs the patient's informed consent to access personal data, we arrive to the opposite situation where the patient needs the physician consent to access his own genetic information. This is why the model of *conditioned consent* represents a distortion, and not a development, of the model of *informed consent*, whose aim is to safeguard the patient's self-determination even in front of a risk for his own health – this also represents the meaning of Art. 32, paragraph 2, of Italian Constitution –, and not the divestment of the patient's freedom of choice.

So we can agree with those who said, about the right of access to predictive medicine, that “unless of specific legislative prohibition, which could even be considered conflicting with fundamental human rights, we should affirm that this right could not be denied”, conclusion required if we consider that “in the construction of privacy, genetic data are more important than every other personal information”²⁵ as they concern the

²⁴ Cfr. ECJ, sez. III, May 7th, 2009, n. 553, C-553/07, *College van burgemeester*, §§ 50 e 51. It must be remembered that the ECJ has said that Directive n. 95/46/CE is (almost totally) self-executing in National law: cfr., ECJ, May 20th, 2003, joined cases n. 465, C-465/00, C-138/01 and C-139/01.

²⁵ Rodotà S. (1991), p. 536. This author, despite he intended the informative self-determination as a fundamental right, makes this assertion only after answering the question “if knowledge has to be intended as an absolute value”, what would be “the effect of a complete and premature disclosure of our biological destiny” and if “two much knowledge wouldn't become a limit for the autonomy and for the free development of every person” (534).

person's structure, and depriving a human being of the control on this information represents an irremediable *vulnus* of the right to privacy, *ex* Art. 1 of E.U. directive n. 95/46/CE, whose aim is to allow the “complete recovery of «a person sovereignty on himself»” and the total control of a person on his private life²⁶.

For this reason, there are doubts in the light of constitutional legitimacy for the rules provided by § 7.2 of the already mentioned *Guidelines*, in which Art. 12 of *Oviedo Convention* is acknowledged – “as decided in Art. 12 of the Oviedo Convention” – prescribing that “predictive genetic test can be performed only for healthcare purpose or for scientific research. It is illegal every other use, for not healthcare-related purposes”.

This rule, beside the explicit acknowledgement of *Oviedo Convention*, must be interpreted in the light of E.U. directive n. 95/46/CE and of Art. 32, comma 2, of Italian Constitution, such a limitation of access to and use of genetic data only addressed for the physician and not to the person who wants to know his own genetic data. Given the *value* of informative self-determination, it should be not allowed to investigate the reason that drives a person to apply for a genetic test – even “just for fun” – while it is possible to limit the physicians' possibility to prescribe genetic tests for aims other than their patients healthcare.

In the same way, we have to interpret the *2007 Authorization* as intended to allow every person to collect his own genetic data. Moreover, we have to consider every obligation set by the law to access to genetic data as a duty of the physician or geneticist who performs the test. That is because healthcare professionals can be subjected to specific informative charges in favor of the person who applies for the test.

Therefore, the Code of conduct of Italian national medical association (*Codice di deontologia della Federazione nazionale degli ordini dei medici chirurghi e degli odontoiatri*), deals with the problem in a way consistent with the Italian Constitution. In Art. 46 it is established that

Test intended to detect or predict congenital defect or hereditary disease have to be explicitly required, in a written form, by pregnant women or by interested people. The physician must provide the patient prior information and a wide and appropriate explanation about test results and their predictive ability [...].

The deontological regulation gives priority to the will of the person who is requiring the access to genetic data, making him the addressee of a general right of information, aimed to reduce as much as possible the gap between a common person and a technician. The physician doesn't have to evaluate the patient's interest in knowing genetic data, on the contrary he must provide the proper information to make his will to know *informed*. This way we have a new, not only therapeutic, but even informational *alliance* between the physician and the (un)patient, intended to create an “informed will” which is the consistent development of the *informed consent* principle, suitable for *DTC* genetic test problem.

²⁶ Rodotà S. (1998), “Relazione per l'anno 1997 del Garante per la protezione dei dati personali”, *Dir. inf. e informatica*, 3, p. 562.

We can find a genetic test regulation concerned with the idea of the “informed will” in the German *Gendiagnostikgesetz (GenDG)*²⁷.

Declared aim of *GenDG* is to settle requirements to perform genetic tests protecting human dignity and the right to informational self-determination (§ 1, “der Würde des Menschen und des Rechts auf informationelle Selbstbestimmung zu wahren”). For *GenDG*, the condition to perform a genetic test is to receive a proper counseling highlighting the nature, the meaning and the aims of the genetic analysis (*Wesen, Bedeutung und Tragweite der genetischen Untersuchung aufzuklären*, § 9). This way, it has been actuated what we can call the principle of “prior counseling” (*Beratungsvorbehalt*), that is considered to be the best way to protect the person when “particularly ticklish features of human existence are involved”, as in case of assisted reproduction and transplantation²⁸.

The solution adopted by the German legislator goes towards the reaffirmation of the *informed will*, because it permits that the access to genetic data do not depends only on a medical prescription, that the patient have to consent to. On the contrary, the genetic test can come from a voluntary choice of the interested person (*die betroffene Person*, § 8), choice that is improved by the advice of the specialist that have to provide the proper information.

GenDG is not against *DTC* genetic test, but it requires the companies to provide the proper information, even hiring a physician or a geneticist. Therefore, for German law, the disclaimers that the companies put on their web pages are not enough, because they have to offer a face to face counseling, specific drafted after the single customer²⁹.

In conclusion, while it is a breach of Italian Constitution and E.U. law to deny a person to access to his personal data and to his genetic data (and therefore to entirely forbid *DTC* genetic tests), it is possible to the legislator to surround the right of access to genetic data with certain measures, intended to safeguard from health-related or psychological harm.

4. Genetic Tests Consumers, Biobanks, Scientific Research

If the access to one’s own genetic information cannot be limited by claiming specific medical aims and if not even a geneticist can investigate the reason by which a person wants to scan his own genome (even “just for fun”), than it cannot be disowned every-one’s right to give DNA sample for scientific research, obviously protecting the privacy of the ones to whom obtained information refers.

Casus is provided once again by the commercial strategies of American companies involved in *DTC* genetic tests. Some of them made a biobank with the biological sample

²⁷ Gesetz über genetische Untersuchungen bei Menschen, July 31th 2009, in force since February 1st, 2010. For a commentary see Diurni A. (2010), “Esperienze di regolamentazione della diagnostica genetica”, *Danno e resp.*, 7, p. 660 ss.

²⁸ Diurni A. (2010), p. 661 ss.

²⁹ Kaye J. (2008), p. 2 ss. This author tells about a shift in the services supplied by *dtc* genetic test companies, which provides disclaimers about the meaning of the collected information and propose (sell?) a genetic counseling to their customer within the test.

provided by their consumers. By now, several companies ask their costumers to consent the treatment of their data for scientific research, and even to participate the research by fulfilling information about their phenotype *via* internet.

These are the so-called “web-based, participant-driven studies”. People who submit their genetic sample are asked to fill in a questioner in which they give useful information to determine the possible connection between a gene and a manifested character³⁰.

The chance of getting “involved in a new way of doing research” because “with enough data, we believe 23andWe [that is the name of the project realized by the company 23andme] can produce revolutionary findings that will benefit us all”³¹; the chance to get discounts by giving the consent for data treatment, even the opportunity to vote, together with other customers, and choose democratically where to destine the resources that the company sets apart for scientific research (f.i. to finance projects to cure a disease rather than another one) cast doubt in relation to the prohibition of making human body and human genome a profit source³².

That prohibition is not broken because of the non-commercial aim of data treatment, which is scientific research and the direct knowledge of genetic information, which are values protected by Italian Constitution and E.U. treaties. In this scenario every person, even if he is not a scientist, exercise in this peculiar way the freedom of scientific research just as an owner of his own genetic pool, allowing data treatment into a research protocol in exchange of a benefit that can even be immediate (a discount on the test price, the right to improve research in a personal-interesting field, maybe because it regards a pathology that affects his own body or a relative).

This way another subject, the customer, has come to that *crowded footpath in a rainy windy day* that represents the cross-roads of rights and interests to be balanced in scientific research field³³. Using one’s own genetic pool seems to be one of the ways that anyone, not only the scientist with the proper expertise, can exercise his freedom of scientific research or, more properly, the freedom to protect his own health by using the findings of biotechnological research³⁴.

Supply DNA sample for a biobank is also a way to know ourselves, an occasion of the freedom of scientific research, which is not necessary related to an improvement in healthcare possibilities. The first few *web-based studies* aren’t directly intended to get information for new drugs or new therapies, but they are intended to a deeper knowl-

³⁰ Eriksson N., J.M. Mcpherson, J.Y. Tung, L.S. Hon, B. Naughton *et al.* (2010), “Web-based, Participant-Driven Studies Yield Novel Genetic Association for Common Traits”, *PLoS Genet*, 6(6), p. 1 [cit. Pubmed]. This is one of the first paper written by dtc genetic test companies employees to be published by a scientific review. The provided questionnaire asked to reveal the displays of some common traits which genomics already associates to a known gene (freckles, red hair, photic sneeze, the ability to smell the urinary metabolites of asparagus, etc.). This study has been made to prove that “web-based, participant-driven” work, so they can be used as a valid research protocol for more ambitious field of research.

³¹ This way on 23andMe web page, <<https://www.23andme.com/research>>.

³² Prohibition decided by Art. 3, comma 2, of the Charter of Fundamental Rights of the European Union (so-called Nizza Charter), and by Art. 21 of the Oviedo Convention, Rodotà S. (2006), *La vita e le regole*, Feltrinelli, Milano, p. 187 ss.

³³ Bin R. (2005), *La Corte e la scienza*, in D’Aloia A. (ed.), p. 14.

³⁴ Bin R. (2005), p. 14.; Orsi Battaglini A. (1990), “Libertà scientifica, libertà accademica e valori costituzionali”, *Nuove dimensioni nei diritti di libertà*, Cedam, Padova, p. 89.

edge of the human being. For this reason this way to participate in a scientific research protocol is directly related with the right to informative self-determination, because it helps in understanding how our gene pool contributes to make us what we are.

Therefore, even in this case, the choice to consent the use of our personal data cannot be hindered, even if there is a bargain between the genetic test company and the genetic test consumer which involves economic benefits. On the contrary, as we saw before, the choice to apply for a genetic test and to supply genetic data for scientific research should be assisted with a *surplus* of information, in order to create a full informed will. So, information should be given not only about the nature, the meaning and the aim of genetic analysis, but even about data treatment, DNA sample storage, research purposes, research protocol duration, possible influences on donor's health, possibilities to protect donor's informative self-determination, even in the future.

5. The Interference between Bills of Rights

The examination DTC genetic tests market has required the analysis of several source of law and acts intended to become actual sources of law: the Italian Constitution, statutory law, administrative regulation acts, U.E. directives, international treaties whose ratification has been authorized but not yet executed, the formal declarations of international authorities, professional code of conducts, etc.

All these *lato sensu* normative acts are not always consistent to each other. Differences in regulation don't build a multiplication of the tools available to protect human rights, as supposed by those who uphold the theory of *multilevel constitutionalism*, but they can lead to a short-circuit in regulating the new issues originated by the evolution of biomedical science.

It must be pointed out four different problems which suggest to act carefully in front of the *multilevel constitutionalism*³⁵.

Therefore, it must be (urgently) remembered that:

- a. The interferences between different sources of law cannot be simply recomposed underlining a common axiological content, as human dignity. Science and biomedicine carry a number of problem which cannot be solved using only the principle of human dignity. That principle *has* to be developed, and it *can* be developed by legislative acts in different ways. Each of those developments can be inconsistent with the others. Because of that, the legislator must select one of the different available solutions, and he will be politically accountable for that choice.

³⁵ Luciani M. (2006), “Costituzionalismo irenico e costituzionalismo polemico”, *Giur. cost.*, 2, p. 1660 ss. About the crisis of the sources of law system and about using all kind of materials to interpret a source of law, see Bin R. (2009), *Ordine delle norme e disordine dei concetti (e viceversa). Per una teoria quantistica delle fonti del diritto*, in Brunelli G., A. Pugiotto, P. Veronesi (eds.), p. 55. This author stress out “the clear distinction between what is not a rule or a source of law”, distinction which is fundamental to “protect any individual and his autonomy by private or public power”.

b. When a State ratifies an international treaty which bears a bill of rights, as in the *Oviedo Convention*, the treaty can change the outcome of balancing constitutional rights and constitutional interests which can collide in a single case (and in Italy it certainly will, due to Art. 117, comma 2, of Italian Constitution). If every new right is a new limit for the other rights and interests, the source of law which bears the new right, especially in the field of biomedicine, represents a non neutral axiological (political) option, insofar it represents one of the different points of view about human dignity. This is not an attempt to warn against the ratification of *Oviedo Convention*, (in Italian law, *ratification* is a complex affair which involves constitutional powers of the President of the Republic, the Parliament and the Government) but it must be remembered that *Oviedo Convention* is only one of the different possibilities that the legislator can choose, in accordance to the Constitution.

c. Legal concepts used by different kind of sources of law often overlap, but they are never superimposed, even when they are just the translation of the same word (*privacy – riservatezza*), even when they are the counterpart of the same legal (theoretical) construct in two national *legal systems*³⁶.

Talking about genetic tests, the different notions of (international law) *privacy*, (Italian law) *riservatezza*, and informative self-determination (*autodeterminazione informativa* in Italian law, *informationelle Selbstbestimmung* in German law) share a common core which can be found in different legal system. However, the extension of this concept can obviously be different, and it can also include the right to control personal data circulation and the right of access to information that are still not decoded or even still not integrated into a conventional sign (the *data*). The shift from *informed consent* to *informed will* represents the idea that every person has to be protected from those who want to use his personal data without his consent, but he also must have the right to acquire all the personal data which science can provide.

According to a logical and chronological representation of evolution of *privacy*, *informed will* is the highest point of a three stage journey. First stage is the protection against those who want to acquire personal data despite the intention of the person involved. Second stage is every person's right of access to the data already acquired by a third person. Final stage is the right to informative self-determination, the right to know yourself, even using new technologies given by biomedical science³⁷. It is not obvious nor necessary, indeed, that *privacy*, as protected in any legal system, also acquires the third dimension of the right to informative self-determination, the freedom of in-

³⁶ Sorrentino F. (2005), "La tutela multilivello dei diritti", *Riv. ital. dir. pubbl. comunitario*, 1, p. 79.

³⁷ Reader will detect the similarity between the freedom of using biotechnologies to access to information related to our own person and body and the freedom of using biotechnologies for the exercise of dominion over our own body, for example in the field of medically assisted procreation.

vestigation towards our own body, the right of access to our own genotype (and, therefore, the possibility to apply for a DTC genetic test).

- d. A source of the law can be used as a parameter for the interpretation of another source of law. In previous paragraphs we saw that the disposal of *Oviedo Convention* which allows genetic tests only with medical purpose can be interpreted in two different ways: a prohibition *erga omnes*, aimed to protect human health from the traumatic effects caused by dreadful news, or a limitation which only affects medical professionals and, on the other hand, safeguards every person's freedom to know his own genetic data.

It is easy to choose the second solution if the Convention is interpreted “so far as possible, in the light of the wording and purpose of Directive [95/46/CE] in order to achieve an outcome consistent with the objective pursued by the directive”³⁸. This is because the second interpretation gives value to the principle of free access to personal data, which is an important part of Directive 95/46/CE.

On the contrary, interpreting E.U. law *in the light of the wording and purpose* of the *Oviedo Convention*³⁹ can lead to an opposite outcome, upholding the general prohibition to access to genetic data outside healthcare purpose.

The two interpretative patterns are not changeable and do not lead to the same outcome, so we have to choose the line to follow regarding the constitutional rules about the different sources of law, recomposing in a system (and therefore identifying a system of) the sources of law before we get a short-circuit of all that normative material.

A jurist who operate in a written constitution legal system has to follow the legal skyline drafted by the constitution, and this is because *Oviedo Convention*, as previous paragraphs tried to demonstrate and as it is shown by the abnormal occurrence of its ratification, represents a political choice of the legislator. It is the Parliament, legislative power subjected to the Constitution, which introduce the *Convention* into the legal system with the ratification. As every normative choice yielded by the legislator, it must be submitted to constitutional review, even interpreting international law in conformity with the Constitution, otherwise the constitutional rigidity would be fatally compromised.

³⁸ This is the formula for the principle of interpreting national law in conformity with Community law: ECJ, 4th chamber, July 16th, 2009, c-12/08, Mono Car Styling SA, in liquidation.

³⁹ Luciani M. (2009), *Positività, metapositività e parapositività dei diritti fondamentali*, in Brunelli G., A. Pugiotto, P. Veronesi (eds.), p. 1069 noted that the *Oviedo Convention* has been used by courts before the ratification – Cass. civ., Sez. I, October 16th, 2007, n. 21748 – to achieve an interpretation of national law in conformity with the Convention.

References

- Agosta S. (2005). *Tra ragionevoli preoccupazioni di tutela ed irragionevoli soluzioni normative*, in D'Aloia A. (ed.). *Bio-tecnologie e valori costituzionali*. Giappichelli, Torino.
- Bin R. (2005). *La Corte e la scienza*, in D'Aloia A. (ed.). *Bio-tecnologie e valori costituzionali*. Giappichelli, Torino.
- Bin R. (2009). *Ordine delle norme e disordine dei concetti (e viceversa). Per una teoria quantistica delle fonti del diritto*, in Brunelli, G., A. Pugiotto, P. Veronesi (eds.). *Scritti in onore di Lorenza Carlassare*. Jovene, Napoli.
- Bucci L.M., M. Raganella, A. Ventura, F. Ventura, R. Celesti (2005). "Osservazioni etiche e implicazioni medico-legali in materia di "test genetici". *Medicina e morale*, 4.
- Casini M., C. Sartea (2009). "La consulenza genetica in Italia". *Medicina e morale*, 6.
- Chieffi L. (2010). *Analisi genetica e tutela del diritto alla riservatezza. Il bilanciamento tra il diritto di conoscere e quello di ignorare le proprie informazioni biologiche*, in Lucrezi F., F. Mancuso (eds.). *Diritto e vita*. Rubbettino, Soveria Mannelli.
- Cirillo F.M. (2002). "Luci ed ombre del progresso scientifico sul genoma umano. I test genetici e il c.d. diritto 'di non sapere'". *I diritti dell'uomo*, 2.
- De Franco R. (2007), *Art. 90*, in Bianca C.M., F.D. Busnelli (eds.). *La protezione dei dati personali. Commentario al D. Lgs. del 30 giugno 2003, n. 196 ("Codice della Privacy")*. Cedam, Padova.
- Diurni A. (2010). "Esperienze di regolamentazione della diagnostica genetica". *Danno e responsabilità*, 7.
- Ehmann H. (1998). "I principi del diritto tedesco in materia di trattamento dei dati personali con riguardo alla direttiva comunitaria del 24 ottobre 1995". *Contratto e impresa in Europa*, 2.
- Eriksson N., J.M. Mcpherson, J.Y. Tung, L.S. Hon, B. Naughton *et al.* (2010). "Web-based, Participant-Driven Studies Yield Novel Genetic Association for Common Traits". *PLoS Genet*, 6(6), p. 1.
- Gainotti S., A.G. Spagnolo (2004). "Test genetici, a che punto siamo in Europa?". *Medicina e morale*, 4.
- Garofano L., V. Mele (2001). "Approccio bioetico e biogiuridico". *Medicina e morale*, 1.
- Jonsen A.R., S.J. Durfy, W. Burke, A.G. Motusky (1996). "The Advent of the "Unpatients". *Nat Med*, 2(6).
- Kaye J. (2008). "The Regulation of Direct-to-Consumer Genetic Tests". *Hum Mol Genet*, 17.
- Luciani M. (2006). "Costituzionalismo irenico e costituzionalismo polemico". *Giurisprudenza costituzionale*, 2.
- Luciani M. (2009). *Positività, metapositività e parapositività dei diritti fondamentali*, in Brunelli G., A. Pugiotto, P. Veronesi (eds.). *Scritti in onore di Lorenza Carlassare*. Jovene, Napoli.
- Manetti M. (2009). "La sentenza sulla pma, o del legislatore che volle farsi medico". *Costituzionalismi.it*.

- Modenesi C. (2006). *Dal riduzionismo della natura, alla natura del riduzionismo*, in Modenesi C., S. Masini, I. Verga (eds.). *Il gene invadente*. Baldini Castoldi Dalai, Milano.
- Orsi Battaglini A. (1990). “Libertà scientifica, libertà accademica e valori costituzionali”. *Nuove dimensioni nei diritti di libertà*. Cedam, Padova.
- Pace A. (2006). *Art. 21. La libertà di manifestazione del proprio pensiero*, in *Commentario della Costituzione*, G. Branca (ed.), Zanichelli-II Foro italiano, Bologna-Roma.
- Petrone M. (2007). “Trattamento dei dati genetici e tutela della persona”. *Famiglia e diritto*, 8(9).
- Rodotà S. (2006). *La vita e le regole*. Feltrinelli, Milano.
- Rodotà S. (1997). “Persona, riservatezza, identità”. *Rivista critica di diritto privato*, 4.
- Rodotà S. (1991). “Privacy e costruzione della sfera privata”. *Politica del diritto*, 4.
- Rodotà S. (1998), “Relazione per l’anno 1997 del Garante per la protezione dei dati personali”. *Diritto dell’inf. e dell’informatica*, 3.
- Sorrentino F. (2005). “La tutela multilivello dei diritti”. *Rivista italiana di diritto pubblico comunitario*, 1.
- Trojsi A. (2008). “Sulla tutela dell’identità genetica del lavoratore”. *Giornale di diritto del lavoro e delle relazioni industriali*, 117.
- “Wellcome Trust Case Control Consortium, Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls”. *Nature*, 2007 June 7, 447(7145).
- Zeno-Zencovich V. (2009). “La comunione di dati personali. Un contributo al sistema dei diritti della personalità”. *Diritto dell’informazione e dell’informatica*, 1.

Biosimilars Regulation between Safety and Economic Concerns: A Comparative Analysis

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Abstract: Patent system is conceived as an instrument to correct one of the market's imperfections. A limited-in-time monopolistic right is granted to the inventor in exchange of every detail regarding the invention and, at the same time, it constitutes the primary incentive for scientific research, especially in the pharmaceutical field. Society's interest in having access to the invention at a reasonable price should become more concrete when patent expires. However, for pharmaceutical products, this passage is not that automatic. The generic version of a medicine has to undergo a long series of clinical and non-clinical studies which ought to attest the equivalence with the branded drug. Moreover, when it comes to biotechnology drugs, their complexity along with other obstacles do not allow the creation of a perfect equivalent which can be marketed soon after patent expiration. Nonetheless, recognizing the effectiveness of biotech drugs and the benefits related to their commercialization at a lower cost, legislators are trying to provide means by which biosimilars may obtain a faster marketing approval while maintaining high safety, quality and efficacy standards.

Contents: 1. The Difficult, and Apparently Unavoidable, Relationship between Pharmaceuticals and Patents - 2. Biotechnology Drugs: Differences and Problems - 3. A First Solution: Exclusivity rights - 4. A Second Solution: Faster procedures to obtain marketing authorization for biosimilars - 5. A Third Solution: Generic and/or specific guidelines - 6. A Fourth Solution: Minor exclusivity to the first biosimilar - 7. Recent Italian Developments - 8. Conclusion - References

1. The Difficult, and Apparently Unavoidable, Relationship between Pharmaceuticals and Patents

Patents are seen as an instrument of ambivalent nature. They are a monopolistic tool as well as a strong incentive for research in any field of technology. They grant exclusivity but, at the same time, they entail the disclosure of every detail regarding the patented invention, allowing its unconditioned exploitation when the patent expires.

The pharmaceutical sector in particular highlights the oxymoronic essence of patents: medical products protected by them have higher costs, forcing the majority of the needy persons to live without modern cures. At the same time, drugs improvement derives from enormous investments, which no enterprise¹ would undertake without the certainty to recover the money spent and the guarantee of a profit. Since an important part of Research and Development (R&D) projects in the pharmaceutical field is privately financed, patent seems to be an ineradicable incentive/prize instrument².

The time limit of patent protection – usually twenty years³ – is a crucial element in this difficult balancing between opposite but converging interests. When the patent expires, the entire society can finally have access to the invention without any restriction and, almost always, at a lowered price. However, for pharmaceutical products this passage is not that automatic. The so-called “generic” version of a medicine has to undergo a long series of clinical and non-clinical trials, which ought to attest the equivalence

¹ The more science advances and the more difficult it becomes for the single inventor to achieve some significant results. Quite every complex research – such as the majority of the pharmaceutical ones – is not only very expensive but it has to be carried out by a multidisciplinary equipe of scientists, usually financed by a large firm interested in commercializing their discoveries. For some international literature on the matter see, ex multis, Comanor W.S. (2007), *The Economics of Research and Development in the Pharmaceutical Industry*, in Sloan F.A., C. Hsieh, *Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective*, New York; Hartmann A. (2006), *Global Importance of Patents for the International Pharmaceutical Industry*, in Parulekar A., S. D'Souza, *Indian Patents Law: Legal and Business Implications*, Delhi; Katju M. (2004), *Intellectual Property Rights and the Challenges faced by the Pharmaceutical Industry*, in Vaish A. (ed.), *Intellectual Property Rights: Issues and challenges in Pharmaceutical Industries*, New Delhi.

² Patent has often been considered as a contract between the inventor and the society, in which the first one discloses his discoveries in exchange for – limited in time – exclusivity rights. However some scholars argue that for certain kinds of invention such a reward is inappropriate. Pharmaceuticals, in particular, should be considered unpatentable due to their role of life-saving means, useful to the entire mankind. The greater weakness of these theories resides in their incapacity to provide a valid alternative to patent in terms of reward for the inventor, and for the investors which finance the R&D project. See in general Galambos L. (2006), *Innovation and industry evolution: a comment*, in Mazzuccato M., G. Dosi, *Knowledge accumulation and industry evolution: the case of pharma-biotech*, Cambridge; Sood A., V. Ahluwalia (2008), “Questioning the Justifiability of Innovation Protection in Antimicrobial Drugs: A Law and Economics Perspective”, *Nw. J. Tech. & Intell. Prop.*, p. 181; Lichtenberg F.R. (2006), *Pharmaceutical innovation as a process of creative destruction*, in Mazzuccato M., G. Dosi, G.; Gaudilliere J.P. (2008), “How pharmaceuticals became patentable in the twentieth century”, *History and Technology*, 24; Sonderholm J. (2009), “Pharmaceutical Innovation: Law & the Public'S Health: Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics”, *Journal of Law, Medicine & Ethics*, 37, p. 240.

³ In some Countries, for pharmaceutical and phytosanitarian inventions patent duration can be prolonged through the so called Supplementary Protection Certificates (SPCs). Patent protection is shortened by years (up to fifteen) of clinical trials which are necessary to assess safety and efficacy of these products. SPCs try to partially compensate this loss.

with the branded drug. The cited tests and other obstacles⁴ may strongly delay the commercialization of a generic drug, extending *de facto* patent protection. To prevent this, lawmakers all around the world have approved faster procedures to demonstrate the bio-equivalence of a generic drug, while ensuring its safety, quality and efficacy correspond to the ones of the original medicine. A pioneering regulation of this kind was the so called *Hatch-Waxman* Act 1984, enacted in the U.S. to enhance generics trade⁵.

2. Biotechnology Drugs: Differences and Problems

Notwithstanding the undeniable growth of generic drugs production and distribution, the majority of the most advanced medicines available on the market – *i.e.* the biotechnology drugs – continues to be sold in their branded version even after patent expiration, due to the impossibility to demonstrate the perfect bio-equivalence of the “generic” counterpart⁶.

Biological products, more frequently “biologics”, are a particularly effective kind of pharmaceuticals obtained from living organisms and used to treat, prevent or cure various human diseases. Originally, their components were simply extracted from natural sources, such as human and animal blood, tissues or other microorganisms. Thanks to science’s progresses, they are now produced employing various biotechnological techniques – *i.e.* recombinant DNA technology or genetic engineering – and other advanced methods.

⁴ One of the most discussed practices used to extend patent duration is the so called “evergreening”. Pharmaceutical firms try to prolong patent efficacy by delaying the commercialization of the generic version of the drug: they file an application for a patent regarding an already patented invention claiming that they have discovered new usages for the same drug. When the new patent is granted, thanks to the (quite) perfect correspondence of ingredients between the generic drug ready to enter the market and the newly protected drug, the generic medicine cannot be commercialized any more. If it would be, the act could be considered as counterfeiting. For a more detailed explanation see, *inter alia*, Basheer S. (2005), *Limiting the patentability of pharmaceutical inventions and microorganisms: a TRIPs compatibility review*, London, p. 30 ss., and Glasgow L.J. (2001), “Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?”, *IDEA*, 41, p. 227. See even Bouchard R.A., R.W. Hawkins, R. Clark, R. Hagtvedt, J. Sawani (2010), “Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals”, *Nw. J. Tech. & Intell. Prop.*, 8, p. 174, for a comment on a debated decision of the Supreme Court of Canada (*AstraZeneca Can., Inc. v. Canada*, [2006] S.C.R. 560, 2006 SCC 52, P 39 (Can.)) in which it was affirmed that Given the evident (and entirely understandable) commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired, the decision of the Federal Court of Appeal would reward evergreening even if the generic manufacturer (and thus the public) does not thereby derive any benefit from the subsequently listed patents.

⁵ This denomination derives from the promoters of the Act. Its official name is Drug Price Competition and Patent Term Restoration Act 1984 and it contains specific provisions which allow the generics firms to make use of the tests results disclosed from the producer of the branded drug (when it was trying to obtain the marketing authorization). See in general Grabowski H. (2007), *Competition between Generic and Branded Drugs*, in Sloan F.A., C. Hsieh.

⁶ Yang J. (2010), “A Pathway to Follow-On Biologics”, *Hastings Sci. & Tech. L.J.*, 3, p. 217.

More precisely, while traditional drugs typically consist of small molecules derived from a chemical process, biotech drugs are, mostly, protein-based⁷ therapeutic drugs, consisting of large molecules whose properties depend on a combination of various elements.

Biologics' characteristics are usually related to the amino acids composition of the protein, whose number can vary from 3 to more than 2,300 in one single molecule. Other important data are the number of atoms and the molecular weight. Differently from chemical drugs, which usually account for some dozens of atoms with an overall weight of a few hundreds Daltons, an average biological drug has about 5,000 to 50,000 atoms and a molecular weight varying between 15,000 and 100,000 Daltons⁸. These factors determine, other than size and weight, the basic structure of the drug. However, in every single protein amino acids are linked together to make a continuous string which twists, rotates, bends, edges and binds to itself, creating a peculiar three dimensional conformation. The biological activity of the medicine is related to this unique pattern and it is unpredictable basing solely (and simply) to the amino acids composition⁹.

Moreover, biologics always carry with them impurities which cannot be removed and which become part of the drug itself, influencing its action. So, even the manufacturing conditions and the peculiarities of the source-organisms of the drug have a direct effect on the medicine¹⁰.

Another aspect to consider is the frequent instability of biotech drugs. Differently from simple chemical entities, biological compounds tend to easily degrade, they are particularly heat and light-sensitive and they are susceptible to microbial contamination. Consequently, not only production but even transportation and preservation conditions play an important role in bio-therapeutics¹¹.

Lastly, some biologics can induce allergic reactions and/or immune responses in the body, which starts to produce undesired antibodies. As highlighted in the *Epogen-Eprex* case, immunogenicity concerns are a serious matter and even a slight modification of the drug's characteristics can have unpleasant side-effects¹².

⁷ Other than proteins, they can be constituted of sugars, nucleic acids in general, a combination of such substances and so on; sometimes they are complete living entities like cells and tissues. See Gitter D.M. (2008), "Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States", *Fla. St. U.L. Rev.*, 35, p. 555.

⁸ See, ex multis, Sahr, R.N. (2009), "The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition", *B.C. Intell. Prop. & Tech. F.*, 70201; Tzeng L. (2010), "Follow-on Biologics, Data Exclusivity, and the FDA", *Berkeley Tech. L.J.*, 25, p. 135; Vernon J.A., A. Bennett, J.H. Golec (2010), "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics", *B.U. J. SCI. & TECH. L.*, 16, p. 55.

⁹ Sahr R.N. (2009).

¹⁰ Gitter D.M. (2008). Moreover, it has to be noted that the influence of manufacturing conditions on the final product is a serious issue not only for the difficulty to recreate those conditions when developing the generic (or, better, biosimilar) version of a biological drug. The real problem is that the original producer is not obliged to reveal every detail of the facility in which it produces the biotech drug and consequently nobody can know precisely the optimal production's details. Besides, a pharmaceutical is usually covered not only by a product patent (which regards the product itself) but even by several process patents, which protect (while, at least, revealing it) every new mechanism of production.

¹¹ As underlined by Yang J. (2010).

¹² Both Epogen and Eprex were drugs containing the same active ingredient, epoetin alpha, which is similar to the naturally human-produced erythropoietin. Epogen was commercialized in the US, while Eprex was

The said complexity of bio-engineered drugs makes the R&D phase and the Clinical Trials phase very long and expensive¹³. The effective duration of the patent is considerably shortened and the active costs are estimated to be about 150% of those related to a chemical drug¹⁴. Quite as a paradox, the same biologics' complexity causes these medicines to be easier to counterfeit, with reduced possibilities to demonstrate the violation of the patent owner rights and to stop any illegal activity¹⁵.

All these circumstances directly affect the final cost of the products, which is often so high¹⁶ – reaching peaks of € 450.000 for an annual treatment¹⁷ – that States with control over the price of medicines do not even import them. This is one more reason which brings the attention towards non perfectly bio-equivalent versions of biotech drugs, called biosimilars¹⁸. In fact, they are seen as a good alternative which could help in cutting down the price of important drugs, making them more affordable. At the same time, due to their proven efficacy, biologics' R&D has to be stimulated and not slowed down. Branded drugs and generic (or biosimilar) ones have both their own crucial importance, thus requiring a balanced regulation.

3. A First Solution: Exclusivity rights

As already highlighted, developing a new biological product is extremely expensive. The long series of clinical trials and non-clinical studies necessary to obtain the Marketing Authorization¹⁹ may result in a significant erosion of patent protection. As a consequence, appointing an unconditioned fast way to introduce biosimilars into the market could remove a substantial advantage of actual R&D within biologics field: they are relatively difficult to imitate and the branded drug dominates the market long after patent expiration²⁰. This situation permits pharmaceutical companies to recover the expenses and earn

sold outside US, mainly in Europe. However, patients treated with Eprex – derived from an alternative source and differently administered – developed a greater immune reaction which led them not only to reject the drug but epoetin alpha itself. Even worse, some patients did not tolerate any more their self-produced erythropoietin, with dramatic health consequences. Compare on the matter Sahr R.N. (2009), Gitter D.M. (2008) and Kaldre I. (2008), “The future of generic biologics: should the United States “follow-on” the European pathway?”, *Duke L. & Tech. Rev.*, 1.

¹³ As highlighted in Yang J. (2010), while a common chemical drug requires about 40-50 clinical tests, the average biological drug needs at least 200-250 tests to prove its safety, efficacy and quality.

¹⁴ Vernon J.A., A. Bennett, J.H. Golec (2010) and Grabowski G. (2007), “The Cost of Biopharmaceutical R&D: Is Biotech Different?”, *Managerial Decision Econ.*, 28, p. 469.

¹⁵ Sahr R.N. (2009).

¹⁶ See also McCaughan M. (2010), “Follow-on Biologics: Getting Past the Exclusivity Debate”, *Managed Care*, 19 (7)(2).

¹⁷ For a comparison and an illustration of the prices' situation see, inter alia, Tzeng L. (2010).

¹⁸ As underlined in Bouggy B.R. (2010), “Follow-On Biologics Legislation: Striking a Balance Between Innovation and Affordability”, *Ind. Health L. Rev.*, 7, p. 367.

¹⁹ Every pharmaceutical needs a marketing authorization – from national competent authorities – to avoid the unimaginable danger that an uncontrolled circulation of potential toxic medicines would cause.

²⁰ See in general Grabowski H. *et al.* (2007), “Entry and Competition in Generic Biologics”, *Managerial Decision Econ.*, 28, p. 439 and Grabowski H., I. Cockburn, G. Long (2006), “The Market for Follow-On Biologics: How Will It Evolve?”, *Health Affairs*, 25, p. 1291.

considerable gains. On the other side, without specific procedures to approve and commercialize biosimilars in a reasonable time, they could never reach the market.

A first solution proposed, and adopted by some legislators, is to provide temporary exclusivity rights for the original biological products which obtain marketing authorization²¹. “Exclusivity rights” are a peculiar form of intellectual property which receives, within the various legislative provisions, different denominations to which correspond different juridical effects. With reference to pharmaceuticals, we commonly find marketing exclusivity rights and data exclusivity rights²².

A company trying to obtain marketing authorization for a generic drug can usually rely on the data disclosed – while seeking the first²³ marketing authorization – by the firm which created the original product, indicated as “reference product”²⁴. Data exclusivity implicates that, for a certain period, the generic company cannot relate on those data to demonstrate the bio-equivalence or the bio-similarity of the drug. This means that an hypothetic request of marketing authorization filed in that period would be treated as a normal – and not a generic – application. Consequently, quality, safety and efficacy of the medicine should be ordinarily demonstrated, without benefiting of any kind of accelerated procedure. Complementary to data exclusivity, marketing exclusivity prevents that, until the end of a certain period (usually longer than the data exclusivity one), no generic product relying on a particular reference drug can enter the market.

Since exclusivity rights begin from the moment marketing authorization is granted, independently of the length of the related procedures, they compensate for the possible deficiencies of the patent system²⁵.

One of the first international players that introduced exclusivity rights for pharmaceuticals, irrespective of their being or not biologics, were the U.S.: for example, every

²¹ In reality the solution, already present in the Hatch-Waxman Act, finds now a solid international basis in Art. 39 TRIPS. In particular, Art. 39, p. 3 TRIPS states that Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Due to the uncertainty of its interpretation – and to the lack of a precise term of protection – the mentioned provision does not receive uniform application within the WTO Member States. Sometimes, it does not receive any application at all.

²² Sometimes the law does not distinguish between marketing and data exclusivity, using the two different terminologies as they were interchangeable. However, because the effects are not the same and for the sake of clarity, in this paper they will always be kept separated. For a good explanation of the differences see Morgan M.R. (2010), “Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism”, *Colum. Sci. & Tech. L. Rev.*, 11, p. 93.

²³ It is important to note that these exclusivity rights are conceded only once and with reference to the first marketing authorization. In fact, for the same drug could be requested different subsequent authorizations regarding, for example, changes in dosage.

²⁴ The reference product can be only one. Otherwise there could not be any equivalence (nor similarity).

²⁵ See on this point Mireles M.S. (2004), “An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation”, 38 *U. Mich. J.L. Reform* 141, pp. 174-94. The Author goes even further, saying that marketing exclusivity is better than a patent. In fact, some biologics could result unpatentable for a lot of reasons and still be protected by a good exclusivity system, which could serve as a strong, and supplementary, incentive for research in this important and critical field. See even Grabowski H. (2008), “Follow-on biologics: data exclusivity and the balance between innovation and competition”, *Nature Reviews*, and Vernon J.A., A. Bennett, J.H. Golec (2010).

authorized drug containing a New Chemical Entity (NCE)²⁶ was granted a 5-years data exclusivity and every medicine classified as “orphan drug” – within the meaning of the so called Orphan Drug Act 1983²⁷ – was granted a 7-years marketing exclusivity. The recent U.S. Health Care reform introduced a new policy with specific regard to biotechnology drugs: a biosimilar application (to which has been associated an expedited procedure) cannot be filed until at least 4 years have passed from the first marketing authorization of the reference product and, more significantly, no biosimilar can be approved before 12 years have passed from the same authorization²⁸.

Also with the objective to conform with art. 39, p. 3 TRIPs²⁹, other national and supra-national authorities followed. Just to mention some of them, in 1995 Canada introduced a 5-years data exclusivity period with an amendment to its *Food and Drug Regulations*³⁰, extending it to 6 years in 2006 while providing an additional 8-years marketing exclusivity³¹. Australia implemented a 5-years data exclusivity for NCE with the *Therapeutic Goods Amendment Act 1998*³²; China, in 2002, enacted new *Implementing Regulation of Drug Administration Law* to ensure a 6-years data protection³³; Japan, under art. 14, p. 4 of the *Pharmaceutical Affairs Law*, assures a 4-years data exclusivity combined with a 6-years marketing exclusivity³⁴.

European Union introduced a modern discipline of exclusivity rights, regarding all types of pharmaceuticals, through Directive 83/2001/EC, which obliged Member States to provide data exclusivity rights for a period varying from 6 to 10 years. Afterwards, Directive 2004/27/EC stipulated that an 8-years data protection, accompanied by a 10-years marketing exclusivity, should have been provided³⁵. Subsequently, Regulation

²⁶ In other words, an application which does not rely on previously approved (by the administrative authority) active ingredients.

²⁷ Precisely, Public Law 97-414, 4 January 1983 amending the Federal Food, Drugs and Cosmetic Act. In particular it is considered an orphan drug every pharmaceutical whose purpose is to treat or cure a rare disease. Ex Section 526, p. 2 of the amended act, a rare disease or condition means any disease or condition which occurs so infrequently in the United States that there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.

²⁸ The reference goes to the Biologics Price Competition and Innovation Act 2009, which amended Section 351 of the Public Health Service Act (42 U.S.C. 262) introducing a subsection (k) titled “Licensure of biological products as biosimilar or interchangeable”. For some comments see, ex multis, Nash S.A., Workman R. (2010), “A New Pathway for Follow-On Biologics”, *Fed. Cir. B.J.*, 20, p. 193 and Sahr R.N. (2009). It has to be noted that both the data exclusivity and the marketing exclusivity periods can be extended of other six months if the disclosed information relating to the use of a new biological product in the pediatric population may produce health benefits in that population. Besides, if the biological product refers to a rare disease, the data exclusivity period remains 7 years (or 7 years and 6 months if the drug’s information produces health benefit in a “pediatric” population).

²⁹ See supra at note 22.

³⁰ In particular Section C.08.004.1.

³¹ Or 8 years and 6 months if the manufacturer discloses important pediatric studies.

³² Which amended the Therapeutic Goods Act 1989.

³³ Precisely in Chapter V, art. 35 of Implementing Regulations of the Drug Administration Law of 4 August 2002.

³⁴ The marketing exclusivity period can be extended up to 10 years if the drug is an “orphan drug”. The discretionary judgement is conducted by the Minister of Health, Labour and Welfare (MHLW).

³⁵ The marketing exclusivity can be extended of one more year (getting up to 11 years in total) if an additional therapeutic indication of the same drug is indicated. See for some comments Mounho B., A. Phillips, K. Holcombe, G. Grampp, T. Lubiniecki, I. Mollerup, C. Jones (2010), “Global Regulatory Standards for the Approval of Biosimilars”, *Food Drug L.J.*, 65, p. 819.

2004/726/EC – establishing, *inter alia*, the European Medicines Agency (EMA), responsible for Communitarian marketing authorizations – consolidated, in its art. 14, p. 11, the cited discipline.

Trying to tailor a balanced regulation, legislators had begun to grant exclusive marketing rights, as well as data protection, primarily to those companies which discover new active ingredients. The correlated research is very expensive and time-consuming, especially when it comes to biologics. Nevertheless, the U.S. are the first country to provide a specific, and more beneficial, exclusivity for biotechnology drugs alone. An example that could be imitated soon.

4. A Second Solution: Faster procedures to obtain marketing authorization for biosimilars

In the attempt to find a fair solution, some of the same lawmakers which had conceded exclusivity rights began to establish new procedures that permit generic companies to obtain a faster approval of their biosimilar drugs. In fact, the impossibility to prove the bio-equivalence with the original patented biological drug leads solely to the creation of “similar” products, whose quality, safety and efficacy have to be evaluated with a case by case approach. This situation does not permit biosimilar applicants to avail themselves of the accelerated “marketing approval pathways” at the disposal of common chemical-drugs generic manufacturers, creating an evident disparity which afflicts biosimilars market. At the same time, it is self-evident that the extreme complexity of biotechnology drugs³⁶ imposes a greater attention when trying to assess biosimilarity, and so in the evaluation of the related comparative studies.

European Union, through Directive 2001/83/EC, introduced a faster procedure to obtain marketing approval for biosimilar drugs³⁷. Art. 10 of the same Directive states that “the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product³⁸”.

³⁶ Whose risks are not related solely to patients’ health. Explicative on the matter is Considering n. 36 of Reg. 726/2004: Environmental risks may arise from medicinal products containing or consisting of genetically modified organisms. It is thus necessary to subject such products to an environmental risk-assessment procedure similar to the procedure under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, to be conducted in parallel with the evaluation, under a single Community procedure, of the quality, safety and efficacy of the product concerned.

³⁷ After the application is sent to the EMA, the evaluation is then carried out by the Committee for Medicinal Products for Human Use (CHMP). If the CHMP concludes that the product’s quality, safety, and efficacy are sufficient, it adopts the so called “positive opinion”. Afterwards, this opinion is sent to the European Commission, which transforms it into a single marketing authorization valid throughout the European Union.

³⁸ Ex Directive 2001/83/EC, art. 10, p. 1.

However,

where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products³⁹, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided [...]. The results of other tests and trials from the reference medicinal product's dossier shall not be provided⁴⁰.

An annex to the Directive contains a detailed, but still synthetic, description of what is generally needed to establish quality, safety and efficacy of a biosimilar drug, demanding further explanations to guidelines released by EMA.

Similarly, the recent U.S. *Biologics Price Competition and Innovation Act* (BPCIA) 2009 outlines a new procedure to obtain a faster approval for biosimilar drugs, while requiring a long list of studies and clinical trials. Besides, if an applicant is seeking a declaration from the U.S. Food and Drug Administration (FDA) – the authority in charge of granting the marketing authorization – that the drug is completely interchangeable⁴¹ with the reference product, further studies have to be provided. Even Japan, another important player in the pharmaceutical market, has recently enacted a similar legislation.

However, it has to be noted that the just mentioned “accelerated procedures” are rarely real procedures. More often, biosimilar applications follow the normal “new drug” application pathway with a slight “discount” on studies and data to be provided. Besides, if we combine this system with the case-by-case approach followed to evaluate biosimilars, we notice that additional tests could be required anytime. The lack of clarity and precision proper to these “procedures” is one of their weak points but it is, at least in part, understandable in light of the complicated and delicate matter at hand. The situation is less acceptable when, as the case of Canada, the law does not even mention on what basis biosimilars will be evaluated nor it guarantees any kind of reduction in the data required to obtain marketing authorization. Neither the guidelines provided by Health Canada – Canadian authority responsible for marketing authorization – contain

³⁹ Directive 2001/83/EE, art. 10, p. 2, l. (b) stipulates that ‘generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant [...].

⁴⁰ Ex Directive 2001/83/EC, art. 10, p. 4.

⁴¹ Ex BPCIA (but this is a commonly accepted definition), a biosimilar (recognized as such) is interchangeable when for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

any reference to an abbreviated procedure or to unneeded studies to prove biosimilarity, which have to follow the normal New Drug Application (NDA) way.

5. A Third Solution: Generic and/or specific guidelines

For biosimilars producers, knowing – precisely and in advance – what kind of trials or studies have to be submitted, and how they will be evaluated, constitutes a great advantage. The regulations which describe the procedures to obtain marketing authorization can never be too accurate: they contain general indications that do not always refer specifically to the characteristics of biological drugs.

Based on this acknowledgement, and recognizing the perils related to an exacerbation of the case-by-case approach, some institutions have begun to create generic guidelines for biosimilar drugs, in which they list a series of conditions to assess their quality, safety and efficacy as well as to render a comparative judgement with respect to the original product.

EMA, before any other authority worldwide, introduced its first “overarching” guideline, valid for every biosimilar application, in 2005⁴². Here, we are talking about an introductory guideline, titled “*Guideline on Similar Biological Medicinal Products*”⁴³, which describes, in general, the regulatory framework, the scope of the document, the pressing need to issue a form of guidance for biosimilars and the basic principles associated with the biosimilarity approach⁴⁴. In 2006, two other generic guidelines on biosimilars containing recombinant DNA-derived proteins were released: a “*Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues*”⁴⁵ and a “*Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Quality Issues*”⁴⁶.

The first addresses the general principles – followed when deciding to grant or not to grant marketing authorization – with regard to the evaluation of clinical and non-clinical studies. More specifically, the document describes the non-clinical information

⁴² More precisely, the 2005 guidelines were anticipated by two other important documents which came into force, respectively, in 2003 and in 2004, and titled Comparability of Medicinal Products containing Biotechnology-derived Proteins as Active Substance – Quality Issues (CPMP/BWP/3207/00 Rev. 1, CPMP/ICH/5721/03) and Comparability of Medicinal Products containing Biotechnology-derived Proteins as Drug Substance – Non Clinical and Clinical Issues (CPMP/3097/02) (this guideline has now been substituted by a new version which came into effect on 1 November 2007, doc. CHMP/BMWP/101695/06). Besides, it has to be noted that already in 1998 a concept paper on Development of a CPMP Guideline on Comparability of Biotechnology-derived Products (CPMP/BWP/1113/98) had been created by what would have become EMA, the then European Agency for the Evaluation of Medicinal Products.

⁴³ Doc. CHMP/437/04 which came into effect on 30 October 2005.

⁴⁴ See on this point Underwood, J.R. (2007), “What the EU has that the US wants: an analysis of potential regulatory systems for follow-on biologics in the United States”, *DePaul J. Health Care L.*, 10, p. 419.

⁴⁵ See Doc. CHMP/42832/05, effective from 1 June 2006.

⁴⁶ Document CHMP/49348/05, effective from 1 June 2006. This guideline is currently under revision: a concept paper named Revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality Issues (CHMP/BWP/617111/2010), has been released and the consultation will end on 31 May 2011.

which should be recollected before trying to obtain the said authorization, mentioning both *in vivo* and *in vitro* studies. It analyses clinical trials with particular reference to pharmacokinetic and pharmacodynamic ones, concluding with the so called efficacy tests. Nonetheless, important details are given with regard to clinical safety, pharmacovigilance requirements and immunogenicity⁴⁷.

The second one is mainly about quality aspects, with a special focus on the evaluation, *inter alia*, of manufacturing processes, physicochemical properties, biological activity, purity and impurities.

Another significant contribution are the guidelines drafted in 2009 by the World Health Organization⁴⁸, which have the advantage to be politically neutral. Thus, they result easier to imitate and to combine with national normative provisions.

Following these examples, Japan, Canada, South Africa, Argentina, Malaysia and many other Countries⁴⁹ are starting to adopt or draft similar generic guidelines⁵⁰. Some others, like India, are directly using existing guidelines without elaborating their own. Even in the U.S., after the recent enactment of the cited biosimilars regulation, the possibility for the FDA to introduce similar guidelines is being discussed⁵¹.

However, because already mentioned biologics' complexity makes it impossible to treat them as a uniform category, the need to differentiate from drug to drug is undeniable. That is the reason why some national or supranational authorities have started to release drug-specific guidelines, which take into account the peculiarities of particular kinds of bio-pharmaceuticals.

Once again, EMA has made the first move. Between June and July 2006 the European agency released four Annexes to the quoted *Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues*: the first one regarding similar medicinal products containing *somatropine*⁵², the second one about biosimilars containing *recombinant human soluble insulin*⁵³, the third one referred to similar-pharmaceuticals which use *recombinant erythropoietins*⁵⁴ and the fourth one regarding *recombinant granulocyte-colony stimulating factor*⁵⁵. Then, in April 2009 and in October 2009, EMA released

⁴⁷ About immunogenicity the EMA has released an additional guideline titled "Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins" (CHMP/BMWP/14327/2006), which came into effect in April 2008. Given the seriousness of the matter, this guideline is very detailed, describing with accuracy the factors which can determine the development of an immune response against a therapeutic protein, the strategies to detect and measure immune responses in patients, the clinical consequences of immunogenicity and introducing the necessity of a well structured risk management plan.

⁴⁸ They are the result of Expert Committee on Biological Standardization's work: WHO, Guidelines on Evaluation of Similar Biotherapeutical Products (SBPs), Geneva, October, 2009. The guidelines have been published in the WHO Technical Report Series.

⁴⁹ Korea's Food and Drug Administration released its guidelines in July 2009, Singapore's Health Science Authority in August 2009 and so on.

⁵⁰ Rao G. H.R. (2010), "International Perspectives on Follow-On Biologics", *Managed Care*, 19 (7)(2), and Mounho B., A. Phillips, K. Holcombe, G. Grampp, T. Lubiniecki, I. Mollerup, C. Jones (2010).

⁵¹ Rao G. H.R. (2010).

⁵² Doc. CHMP/94528/05.

⁵³ Doc. CHMP/32775/05.

⁵⁴ Doc. CHMP/94526/05, now superseded by a 2010 version (doc. CHMP/BMWP/301636/08).

⁵⁵ Doc. CHMP/31329/05.

guidelines regarding clinical and non-clinical studies of biosimilars containing, respectively, *recombinant interferon alfa*⁵⁶ and *low-molecular-weight-heparins*⁵⁷. Recently, a draft *Guideline on Similar Biological Medicinal Products Containing Monoclonal Antibodies*⁵⁸ and draft *Guideline on Immunogenicity Assessment of Monoclonal Antibodies Intended for in Vivo Clinical Use*⁵⁹ have been released for comments⁶⁰.

The European strategy consisting in trying to draft a guideline as soon as an important patent expires has been unanimously recognized as a very effective one⁶¹.

6. A Fourth Solution: Minor exclusivity to the first biosimilar

A further step, in the complicated process of creating an equitable legislation regarding biosimilars, has been taken by the U.S. with the introduction of an additional incentive for biosimilars producers. The decision has its roots, primarily, in one acknowledgement: obtaining marketing authorization for biosimilars, in opposition to common generics, is an uncertain, very costly and very long operation. It has been estimated that at least 100 million Euros and 6 to 9 years of work are required⁶².

Basing on this recognition, the BCPIA provides a 1-year marketing exclusivity period for the first biosimilar approved as interchangeable from the FDA. This means that no other sub-sequent biosimilar with the same reference product can receive marketing approval for 1 year, creating a temporary duopoly which permits the first biosimilar to

⁵⁶ Doc. CHMP/BMWP/102046/06.

⁵⁷ Doc. CHMP/BMWP/118264/07.

⁵⁸ Doc. EMA/CHMP/BMWP/403543/2010.

⁵⁹ Doc. EMA/CHMP/BMWP/86289/2010.

⁶⁰ The evaluation period of these guidelines will end on 31 May 2011. Moreover, a concept paper regarding recombinant interferon beta (CHMP/BMWP/86572/10) and a concept paper on recombinant follicle stimulation hormone (CHMP/BMWP/94899/2010) have been released last year and consultations ended in June 2010. The relating guidelines are still being studied.

⁶¹ Basing, mainly, on the mentioned guidelines, EMA has authorized so far several biosimilars. The following list (which can be found, along with further details, at <http://www.ema.europa.eu/>) contains all the biosimilars approved until now: Abseamed (epoetin alfa) (Kidney Failure, Chronic, Anemia, Cancer), authorization released on 28/08/2007; Binocrit (epoetin alfa) (Kidney Failure, Chronic, Anemia), authorization released on 28/08/2007; Biograstim (filgrastim) (Hematopoietic Stem Cell Transplantation, Neutropenia, Cancer), authorization released on 15/09/2008; Epoetin alfa Hexal (epoetin alfa) (Kidney Failure, Chronic, Anemia, Cancer), authorization released on 28/08/2007; Filgrastim Hexal (filgrastim) (Neutropenia, Cancer, Hematopoietic Stem Cell Transplantation), authorization released on 06/02/2009; Nivestim (filgrastim) (Hematopoietic Stem Cell Transplantation, Cancer, Neutropenia), authorization released on 08/06/2010; Omnitrope (somatropin) (Turner Syndrome, Dwarfism, Pituitary, Prader-Willi Syndrome) authorization released on 12/04/2006; Ratiograstim (filgrastim) (Neutropenia, Cancer, Hematopoietic Stem Cell Transplantation), authorization released on 15/09/2008; Retacrit (epoetin zeta) (Cancer, Anemia, Kidney Failure, Chronic, Blood Transfusion, Autologous), authorization released on 18/12/2007; Silapo (epoetin zeta) (Anemia, Blood Transfusion, Autologous, Cancer, Kidney Failure, Chronic), authorization released on 18/12/2007; Tevagrastim (filgrastim) (Neutropenia, Cancer, Hematopoietic Stem Cell Transplantation), authorization released on 15/09/2008; Valtropin (somatropin) (Dwarfism, Pituitary, Turner Syndrome), authorization released on 24/04/2006; Zarzio (filgrastim) (Cancer, Hematopoietic Stem Cell Transplantation, Neutropenia), authorization released on 06/02/2009.

⁶² See, *ex multis*, Foresti G. (2010), "Farmaci biosimilari", *Quaderni SIF*, 22.

conquer part of the market⁶³. However, the fact that the grant of this privilege depends on the declaration of interchangeability makes it very difficult to obtain. After all, the reason undergoing this provision seems clear: since the BCPIA has been adopted (also) with the purpose of reducing National Health Service (NHS) expenditure in combination with the introduction of the reformed health care system, interchangeability becomes crucial. If a product does not possess this characteristic, the original drug will be more difficult to be substituted and part of the purpose of the American amendment will be frustrated.

Nonetheless, an incentive intended to promote the creation of interchangeable biosimilars is perfectly comprehensible. Interchangeability permits an easier substitution and so a relevant reduction in the cost of cures. A provision of this kind seems to be worth imitating.

7. Recent Italian Developments

In Italy, biosimilars' issues and potentials have been recently underlined by the largely publicized intervention of Italian Antitrust Authority⁶⁴ (hereinafter, AGCM, "Autorità Garante per la Concorrenza e il Mercato") against a bill regarding biosimilars – n. 1875 of XVI legislature – pending in Parliament.

The bill contains an amendment to art. 7, l. 405/2001. Said article, in its actual configuration, contains provisions aimed to promote the use of generic pharmaceuticals, in the attempt to reduce National Health Service (NHS) expenditure. Art. 7, p. 1 declares that when a patent for a pharmaceutical expires, the pharmacist will be reimbursed from the NHS for an amount not greater than the price of the cheaper generic version of the same drug available in that Region. Art. 7, p. 3 states that a pharmacist will always inform the patient of the existence of a generic version of a drug and of the possible substitution. In case the doctor clarifies on the prescription to be against the substitution or when a patient refuses it of its own free will, the additional costs will be borne by the patient itself⁶⁵.

The quoted Bill n. 1875 would introduce three important modifications to art. 7 with reference to biosimilars. First of all, art. 7, p. 1 would become inapplicable when in presence of biologics and biosimilars – but even between two or more biologics – of the same class. Secondly, the Bill specifies that a pharmacist cannot substitute a biologic with the corresponding biosimilar when a specific biologic has been prescribed. Thirdly, it is underlined that, to preserve centrality of doctor's decisions over patients' health, the substitution of biotechnology drugs with their corresponding biosimilars – but even with other biotherapeutics of the same class – is prohibited. The provision

⁶³ Marketing exclusivity provided by the BCPIA can be even between 18 and 42 months if a case of patent infringement has been brought to the attention of a Court and depending on the development of the case itself.

⁶⁴ Published on AGCM Bulletin n. 11 of 4 April 2011.

⁶⁵ Ex art. 7, pp. 2 and 4, l. 405/2001.

would apply even in the purchase processes conducted by Health Care Facilities, in the alleged respect of the principle of the “non-therapeutic equivalence”.

While marketing authorization of biologic drugs, including biosimilars, pertains to EMA’s competence, the decision to consider a drug as “interchangeable” is left to the single European Member States. As EMA affirms⁶⁶, “interchangeability” in its pure meaning is very difficult to demonstrate: it means that a biosimilar drug could substitute the originator biologic even in therapies which have been already started with the originator itself. However, the absence of absolute interchangeability does not mean that a biosimilar cannot substitute its originator in the so called “*drug naïve patients*”, that is the subjects which have not yet been treated with the original biologic. If this were not possible, biosimilars existence would be quite meaningless.

Besides, biosimilars undergo a long series of trials and studies which have to prove their safety, efficacy and quality. Every difference between the biosimilar and its originator has to be justified in detail through comparative studies which permit, sometimes, to create an even better drug than the reference product. A similar but, contemporaneously, newer pharmaceutical which can count on the most recent progresses of science.

It is renown⁶⁷ that biologics’ “real” test is the post-marketing phase, when, being distributed on a large scale, immunogenicity issues, allergies and similar problems of the medicine may be clearly highlighted. However, this is a critical issue of every biologic drug, it is not distinctive of biosimilars alone.

If the state of the art makes it impossible, for now, to determine with certainty a complete interchangeability in patients already treated with the originator drug, no reasonable motivation stands in favour of a detrimental discipline for biosimilars when referring to *drug naïve* subjects. In particular, the third proposed amendment contained in the Bill seems to go against the same *ratio* of the law which it could amend: foster competition between generics – or biosimilars – and branded drugs and reducing NHS expenditure while preserving people’s health⁶⁸.

The AGCM seems to share this opinion, recognizing in the mentioned Bill an unjustified limit to competition and, thus, a violation of antitrust law. Italian administrative case law⁶⁹ and the official positions of EMA and AIFA⁷⁰ (*Agenzia Italiana del Farmaco* – the Italian authority competent for national marketing authorizations) seem to confirm this line of thinking.

⁶⁶ The reference goes primarily to the overarching guidelines mentioned. Ravaioli F. (2008), “Dalle guidelines EMEA alla gestione AIFA”, *Atti del workshop nazionale: biotecnologici e biosimilari a confronto*, Rome, and Rinaldi M. (2008), “Il ruolo moderno del farmacista ospedaliero: appropriatezza, sicurezza e management di farmaci biosimilari”, *Atti del workshop nazionale: biotecnologici e biosimilari a confronto*, Rome.

⁶⁷ Ravaioli F. (2008).

⁶⁸ And if with biosimilars a reduction in the global expenditure can be obtained, maybe better drugs could be bought.

⁶⁹ In particular, as underlined by AGCM, the recent decisions of Consiglio di Stato n. 7690/09 and n. 7691/09, of TAR Tuscany n. 1198/10 and of TAR Sardinia 250/11.

⁷⁰ See the various AIFA Information Bulletins, in particular n. 03/2008. There, in particular, Donnarumma E. (2008), “Approfondimento su: farmaci biotecnologici e biosimilari”, *BIF*.

8. Conclusion

Biologics are a delicate matter and biosimilars inevitably share this characteristic.

Concrete and effective incentives for R&D in biotech field are an understandable expectation of pharmaceutical innovators. At the same time, they need to be balanced with procedures that permit the entrance on the market of biosimilars in a reasonable amount of time, while preserving safety, quality and efficacy of the medicines approved. Equally important, the stimulation of biological research does not have to be translated into a series of obstacles for biosimilars.

Internationally harmonized legislative provisions could strongly contribute to achieve said objectives. In fact, even if an increasing number of Countries is introducing special procedures for biosimilars and is drafting detailed guidelines, the differences that may be found between them tend to create a blurry normative framework⁷¹. An uniform position⁷², at least on the scientific principles at the base of the evaluations, should be reached soon. A good initiative, and example, of this kind is represented by the work of the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH)⁷³. With the contribution of the regulatory authorities and the pharmaceutical industry of Japan, EU and USA, the ICH is trying to draw commonly agreed guidelines on the most important aspects of pharmaceuticals evaluation⁷⁴. Recently, even with regard to biotechnology drugs.

⁷¹ For example, EU, Japan and South Africa require that the reference product must have been authorized in those countries before applying for a biosimilar version, Canada does not impose it and WHO guidelines are of the same opinion; most guidelines consider fundamental a comparative study on stability profiles, Japan does not. And so on. See for further details Mounho B., A. Phillips, K. Holcombe, G. Grampp, T. Lubiniecki, I. Mollerup, C. Jones (2010).

⁷² It is, in fact, very strange to notice that the WHO works which resulted into the recently published guidelines had been participated only by a handful of Countries, when the matter is so important and so relevant for every Nation in the world.

⁷³ The official website of the ICH can be found at <<http://www.ich.org>>.

⁷⁴ The most important guidelines drafted by the ICH are the so called "ICH Tripartite Guidelines", which refer to Quality, Safety and Efficacy of pharmaceuticals in general. Besides, for those topics which do not fall entirely into one of the Quality, Safety and Efficacy categories, we have the "ICH Multidisciplinary Guidelines", including the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

References

- Basheer S. (2005). *Limiting the patentability of pharmaceutical inventions and microorganisms: a TRIPs compatibility review*. London.
- Bouchard R.A., R.W. Hawkins, R. Clark, R. Hagtvedt, J. Sawani (2010). “Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals”. *Nw. J. Tech. & Intell. Prop.*, 8.
- Bougy B.R. (2010). “Follow-On Biologics Legislation: Striking a Balance Between Innovation and Affordability”. *Ind. Health L. Rev.*, 7.
- Comanor W.S. (2007). *The Economics of Research and Development in the Pharmaceutical Industry*, in Sloan F.A., C.R. Hsieh, *Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective*. New York.
- Donnarumma E. (2008). “Approfondimento su: farmaci biotecnologici e biosimilari”. *BIF*.
- Foresti G. (2010). “Farmaci biosimilari”. *Quaderni SIF*, 22.
- Galambos L. (2006). *Innovation and industry evolution: a comment*, in Mazzucato M., G. Dosi (eds.). *Knowledge accumulation and industry evolution : the case of pharma-biotech*. Cambridge.
- Gaudilliere J.P. (2008). “How pharmaceuticals became patentable in the twentieth century”. *History and Technology*, 24.
- Gitter D.M. (2008). “Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States”. *Fla. St. U.L. Rev.*, 35.
- Glasgow L.J. (2001). “Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?”. *IDEA*, 41.
- Grabowski H. (2007). *Competition between Generic and Branded Drugs*, in Sloan F.A., Hsieh (eds.). *Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective*. New York.
- Grabowski H. et al. (2007). “Entry and Competition in Generic Biologics”. *Managerial Decision Econ.*, 28.
- Grabowski H. (2008). “Follow-on biologics: data exclusivity and the balance between innovation and competition”. *Nature Reviews*.
- Grabowski H. (2007). “The Cost of Biopharmaceutical R&D: Is Biotech Different?”. *Managerial Decision Econ.*, 28.
- Grabowski H., I. Cockburn, G. Long (2006). “The Market for Follow-On Biologics: How Will It Evolve?”. *Health Affairs*, 25.
- Hartmann A. (2006). *Global Importance of Patents for the International Pharmaceutical Industry*, in Parulekar A., S. D’Souza (eds.). *Indian Patents Law: Legal and Business Implications*. Delhi.
- Kaldre I. (2008). “The future of generic biologics: should the United States “follow-on” the European pathway?”. *Duke L. & Tech. Rev.*, 1.
- Katju M. (2004). *Intellectual Property Rights and the Challenges faced by the Pharmaceutical Industry*, in Vaish A. (ed.). *Intellectual Property Rights: Issues and challenges in Pharmaceutical Industries*. New Delhi.

- Lichtenberg F.R. (2006). *Pharmaceutical innovation as a process of creative destruction*, in Mazzuccato M., G. Dosi (eds.). *Knowledge accumulation and industry evolution : the case of pharma-biotech*. Cambridge.
- McCaughan M. (2010). "Follow-on Biologics: Getting Past the Exclusivity Debate", *Managed Care*, 19(7) suppl. 2.
- Mireles M.S. (2004). "An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation". 38 *U. Mich. J.L. Reform*, 141.
- Morgan M.R. (2010). "Regulation of innovation under follow-on biologics legislation: FDA exclusivity as an efficient incentive mechanism". *Colum. Sci. & Tech. L. Rev.*, 11.
- Mounho B., A. Phillips, K. Holcombe, G. Grampp, T. Lubiniecki, I. Mollerup, C. Jones (2010). "Global Regulatory Standards for the Approval of Biosimilars". *Food Drug L.J.*, 65.
- Nash S.A., R. Workman (2010). "A New Pathway for Follow-On Biologics". *Fed. Cir. B.J.*, 20.
- Rao G.H.R. (2010). "International Perspectives on Follow-On Biologics", *Managed Care*. 19(7) suppl. 2.
- Ravaioli F. (2008). "Dalle guidelines EMEA alla gestione AIFA". *Atti del workshop nazionale: biotecnologici e biosimilari a confronto*. Rome.
- Rinaldi M. (2008). "Il ruolo moderno del farmacista ospedaliero: appropriatezza, sicurezza e management di farmaci biosimilari". *Atti del workshop nazionale: biotecnologici e biosimilari a confronto*. Rome.
- Sahr R.N. (2010). "The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition". *B.C. Intell. Prop. & Tech. F.*, 70201.
- Sonderholm J. (2009). "Pharmaceutical Innovation: Law & the Public's Health: Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics". *Journal of Law, Medicine & Ethics*, 37.
- Sood A., V. Ahluwalia (2008). "Questioning the Justifiability of Innovation Protection in Antimicrobial Drugs: A Law and Economics Perspective". *Nw. J. Tech. & Intell. Prop.*, 6.
- Tzeng L. (2010). "Follow-on Biologics, Data Exclusivity, and the FDA". *Berkeley Tech. L.J.*, 25.
- Underwood J.R. (2007). "What the EU has that the US wants: an analysis of potential regulatory systems for follow-on biologics in the United States". *DePaul J. Health Care L.*, 10.
- Vernon J.A., A. Bennett, J.H. Golec (2010). "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics". *B.U. J. SCI. & TECH. L.*, 16.
- WHO (2009). *Guidelines on Evaluation of Similar Biotherapeutical Products (SBPs)*. Geneva.
- Yang J. (2010). "A Pathway to Follow-On Biologics". *Hastings Sci. & Tech. L.J.*, 3.

Drug Courts between Therapeutic Jurisprudence and Neurolaw: Which Model of Addiction?

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Abstract: According to their proponents, Therapeutic Jurisprudence (TJ) is an academic discipline promoting individual well-being through the use of clinical behavioural sciences in application of legal rules and legal practices. Within Drug Courts (“the application of TJ par excellence”) the “disease model of addiction” is a requirement to be accepted, recognized and internalized by drug offenders. Starting from the recognition of the existent debate among this model – expanded even presenting the so called “brain disease” pattern – my paper tries to give a perspective of analysis offering some remarks on how the concept of responsibility is affected by TJ movement and neuroscience’s approach, observing the empirical-therapeutic assumptions developed by Drug Courts.

Contents: 1. Therapeutic Jurisprudence and Drug Courts: How “law and therapy” intertwine - 2. The *Self* and Individual Responsibility - 3. The Problem of Addiction - 4. Conclusive Remarks - References

1. Therapeutic Jurisprudence and Drug Courts: How “law and therapy” intertwine

Speaking about Drug Courts means to consider the contribution of a theory that, more than others, has provided a background to a movement evaluated by some authors as the most significant penal innovation in the last twenty years¹. The theory I am speaking of is that of *Therapeutic Jurisprudence*, even called as TJ.

Nowadays, not only music and theatre have become to be regarded as having therapeutic effects, but even *Juris-prudence*, as an epistemological theory of the law, seems to have received a therapeutic account. In my opinion, of all the definitions have been given to Therapeutic Jurisprudence, the most useful is the one that describes it as the *study of the role of the law as a therapeutic agent*².

More deeply, TJ relies on social sciences, especially on psychology, to guide its analysis of the law: by doing this, it represents a radical departure from traditional legal jurisprudence. We can say that TJ is an *interdisciplinary* study using especially psychological research to deal with legal issues. As a discipline, it has been developed over the last two decades in the United States by two professors, David B. Wexler and Bruce J. Winick.³ They started to work on the interaction between “law and psychology” in the 1970s, exploring the tensions between the interest of society in identifying, analyzing and controlling the behaviour of people with mental health problems and the individual interests of mentally-ill persons⁴. Subsequently, they started to ask whether mental health law was fulfilling the patients’ clinical needs⁵. They claimed that mental health law, as it currently was, could have caused harm to patients, leading to dysfunctional psychological outcomes rather than promoting psychological well-being.

Despite fixed definitions, Wexler and Winick have always claimed that the *therapeutic* pattern, even outside the mental health law, should have been considered as a “lens designed to shed light on interesting and important empirical and normative issues”⁶ related to law practice. As an example, Winick suggested that anything which is at least *in some sense* related to psychological functioning could be characterized as therapeutic.

One of the strength and of the weakness of TJ has been and continues to be the fact that TJ supporters do not clarify deeply the word “therapeutic”. So, the term “therapeutic”,

¹ Miller E.J. (2004), “Embracing Addiction: Drug Courts and the False Promise of Judicial Interventionism”, *Ohio State Law Journal*, 65.

² Wexler D.B. (2008), *Rehabilitating Lawyers: Principles of therapeutic jurisprudence for criminal law practice*, Carolina Academic Press, Durham.

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⁴ Wexler D.B. (1992), “Putting Mental Health into Mental Health Law: Therapeutic Jurisprudence”, *Law and Human Behaviour*, 16(1); Wexler D., B. Winick (1991), *Essays in Therapeutic Jurisprudence*; Stolle D., D. Wexler, B. Winick (2000), *Practicing Therapeutic Jurisprudence: Law as an Helping Profession*, Carolina Academic Press, Durham.

⁵ Wexler D.B. (1990), *An Introduction to Therapeutic Jurisprudence*, in Wexler D.B., *Therapeutic Jurisprudence: the Law as a Therapeutic Agent*.

⁶ Wexler D.B., B. Winick (1996), *Law in a Therapeutic Key: Developments in Therapeutic Jurisprudence*.

in the recent literature, has become synonymous with *rehabilitative*,⁷ – notwithstanding some authors have remarked the imperfect correspondence between the two words –⁸. The shift on the “rehabilitative solution” does not count as a proper answer because it moves the focus on an understanding of a *rehabilitative* effect. It simply conveys the question whether rehabilitative outcomes are adequately therapeutic in that they improve psychological well-being of the individual involved into the legal process.

The issue might be deepened but, considering the scope of this brief paper, I choose to adhere to the thought by which we can think of TJ as *an interdisciplinary study that adopts a normative theory considering legal system as a therapeutic agent, which seeks to enhance the individual’s mental health and rehabilitation through treatment and behavioural changes, therefore promoting the psychological and physical people’s well-being that legal rules and legal practices affect*.

The tension between an individual dimension (interest for person well-being before the court) and a “social” one (tendency to consider TJ as a kind of Restorative Justice⁹) is one of the crucial features by which TJ can be analyzed and understood, correlating the theoretical approach with a the pragmatic one represented by the “movement of Drug Courts”.

The importance of TJ contribution in analyzing the practices and the procedures employed within Drug Courts lies in the statement by which Drug Courts can be evaluated as the application of TJ *par excellence*¹⁰. Basically, whether TJ is the theory, Drug Court is the empirical underpinning that “demonstrate” the functioning of the theory in itself. As a consequence, TJ has given a theoretical grounding to the judicial “revolution” represented” by *problem-solving courts* and in particular that of Drug Courts. If Drug Courts represent the species, problem-solving courts¹¹ are the genus. Briefly, problem-solving courts can be described as specialized tribunals created to manage

⁷ Petrila J. (1996), *Paternalism and the Unrealized Promise: Essays in Therapeutic Jurisprudence*, in Wexler D.B., B. Winick (1996).

⁸ In particular James Nolan has stressed how the rehabilitative and the therapeutic ethos represent two different ideals belonged by the American society in the matter of punishment in criminal law issue. See Nolan J.L. (1998), *The Therapeutic State: Justifying Government at Century’s End*, NYUP, New York.

⁹ The aim of Restorative Justice is strictly linked to a vision of doing justice as an continuous research for other kinds of norms and values and as an inexhaustible discussion on them. It implies a detachment from the mere application of norms and is oriented towards a dia-logos form of justice whose purpose, inside criminal law, is making of penalty a proactive experience, referable to the free-interactions of individuals. See Bianchi H. (1994), *Justice as a Sanctuary: towards a new system of crime control* Indiana University Press, Bloomington. Called sometimes even as Comprehensive Law Movement, the central idea of Restorative Justice is to formulate a new approach to deal with problems, considering law as an agent of positive change that values extra-legal concerns, beyond strict legal rights and duties. The theorization of TJ as an application of Restorative Justice, within Drug Courts, levers on the “alternativity” of TJ as a theory of punishment and as an authentic example of a relational order building which asks offenders (and often victims) to be directly involved in the juridical decision. The element of consent is the core of this “justice without law” that recognizes, as own limit, the dangerous prevalence of an emphatic element within the realization and enhancing of individual satisfied solutions and consequently, the alleged risk that the action of adjudication falls in an emotivist outcome.

¹⁰ See Goldkamp J.S. (2000), “The Drug Court Response: Issues and Implications for Justice Change”, *Albany Law Review*, 63 (“The drug’s courts embrace of a “therapeutic” paradigm is in large part responsible for its rapid success”).

¹¹ See Dorf M.C., J.A. Fagan (2003), “Problem-Solving Courts: From Innovation to Institutionalization”, *American Criminal Law Review*, 40.

specific problems, often involving individuals who need social, mental health or substance-abuse treatment.

The first example of such courts was the establishment of the drug treatment court, founded in 1989 in Dade County's Eleventh Judicial Circuit in Miami, Florida. It was created as a response to the County's increasing number of drug arrests, its overcrowded jails, and to the high recidivism rate of drug offenders in the criminal standard system. Thus, as a policy choice. Problem-solving courts, but especially Drug Courts, are now moving *with* and *within* TJ towards a complete understanding of the psychological dimension of the human being, giving worth to satisfactory outcomes of the individual into the juridical dimension. In sum, both the empirical dimension of problem-solving courts and the theoretical one of TJ converge their interests towards the rehabilitation and optimization of a human well-being through treatment *via* judicial role.

In details, by creating the first Drug Court, the main intent was to establish an intensive court supervision program guided by the judge oversight: thus, it meant holding a program of medical treatment to combat drug addiction, with constant monitoring and encouragement from the judge. So far, therapeutic courts on *drug-problem-solution* developed into a wide set of different programs. In fact, since its first appearance, Drug Court movement has constituted and still constitutes itself as the best alternative to the punitive system: an alternative which seeks to work at the process and procedure level to *re-institutionalize*, to a certain extent in a new and peculiar manner, the penological goals of diversion and rehabilitation, enhancing behavioural changes and self-liberation from addiction, promoting well-being and treatment directly through the criminal justice system. While Drug Courts vary across localities and so they are not exactly the same, we can certainly identify two main categories of them: from one side Drug Courts with a "*pre-plea*" *diversion method* by which individuals are diverted into the drug court system before being convicted. People are only prosecuted if they fail to complete the program. To the other side, "*post-plea*" *sentencing method* which implies to participants to have their sentences deferred or suspended while they are in the program. If a person fails to satisfy program requirements, he will face sentencing. Generally, people are eligible for Drug Courts when they have been charged with possession or a non violent offense, and must have either tested positive for drugs or have a history of substance abuse at the time of the arrest¹².

What really and deeply diversifies Drug Courts from ordinary criminal apparatus is their *novel style* of courtroom practice. More specifically, the attraction of these courts can be tracked down to the emphasis put on the *external motivators* of individual behavioural change, such as the applications of sanctions and rewards. Regarding the set of *sanctions*, generally they can not be negotiated before entering the courts, but it is even common that the defendant agree that he will accept to a particular range of sanctions before the beginning of the treatment. Sometimes the sanction is applied automatically: in this case the offender does not have the possibility to challenge it. The set of sanctions is counterbalanced by a set of *rewards* that are essential to the behaviour

¹² Fuellen R., J. Trone (2000), "Do Drug Courts Save Jail and Prison Beds?", report written by the New Vera Institute of Justice, New York 2000. [Online], URL: <<http://www.vera.org/download?file=267/IIB%2BDDrug%2BCourts.pdf>>.

modification and treatment acceptance: one common reward in some courts, among others, is the mere renounce by the judge to impose a determined sanction in case of a failure of a certain objective of the program by the defendant. Rewards can be even characterized by prizes, graduation ceremonies or, as an example, the possibility of the expunger of the drug arrest upon successful completion of the program¹³.

According to TJ proponents, the system of rewards guarantees a sense of achievement and awareness from addiction's freedom, fostering self-esteem, motivation and dignity. Moreover, among the techniques used by the judge in order to motivate offenders to submit to the treatment program requirement, there is public shaming. Adding that, the judge can inquire in any particular aspect of the personal life of the defendant, even asking questions that may inculcate the defendant in criminal activity. Throughout the determined program, offenders participate in various treatment modalities, including counseling sessions, periodic urinalysis test and continuous reports to a judge, who oversees the whole process¹⁴. If the offender successfully ends the program, judges can offer praise, applause and prizes (rewards)¹⁵. On the other hand, if the individual fails to comply with the determined prefixed treatment, the court imposes sanctions (other kinds are, for example, community service, increasing participation in 12-step group, or short periods in the county jail).

2. The *Self* and Individual Responsibility

Following the analysis conducted by plural scholars inside the Drug Courts, one of the TJ weaknesses can be traced looking at the superficial and sketchy way in which addiction is defined. In fact TJ looks at addiction as a problem, but it does not deepen the research on this field, telling us on which basis it can anchor its therapeutic intervention. One of the kind of contributions to the issue is the recognition of the importance of the dimension of the *self* as an authentic target on which the judge has to operate in order to *solve* the problem of addiction. And this is all, and maybe not enough. Even if this kind of attention and cure might be sustained by a kind of moral intuition held by the judge, that addiction should be an occasion of mitigation and "compassion", TJ leaves a mark and moves its steps typically using the legal system, in particular the role

¹³ Sanctions are seen as "providing help", "restructuring the defendant's lifestyle", "smart punishment", "motivational jail", or a "response", see Nolan J.L. (2003a), "Redefining Criminal Courts: Problem-solving and the meaning of Justice", *American Criminal Law Review*, 40.

¹⁴ See Nolan, J.L. (2003b), *Reinventing Justice, The American Drug Court Movement*, Princeton University Press, Princeton.

¹⁵ For example, successful defendants, who end the program within Drug Courts, are "graduated" during festive ceremonies. These graduations inside courtrooms include partied speech by the judges and the graduate, balloons, distributions of presents like pens, mugs, T-shirt and often they are concluded with a big hug from the judge. Morris Hoffman recalled a typical dialogue between a therapeutic judge and a client in Compton, California inside a Drug Court: "I let [the defendant] come into my chambers... All she wanted was an hug... So, I just gave her an hug. I mean, what would you do if your child came up to you, and said, 'May I have a hug?' You wouldn't say 'Well, let me think about this now. You have been bad fifteen times.' You would just do it. So, that is what I did. And yes, you should [give hugs]. You get a whole lot back. You really do".

of the courts, seeming to confirm the criminalization of the individual conduct without using legal substantial categories.

In particular, in doing so, it lacks to direct its multidisciplinary “field of inquiry” into a complete understanding of “the problem”, regarding the possible tensions between the phenomenon of treating addiction, together with criminal policing and individual legal responsibility. Starting from this lacking, we can look at TJ as a discipline that overemphasizes the psychological dimension of the *problem*, failing in elaborating an exhaustive claim on how addiction has to be viewed by criminal law. So, my intent is to remark what, as a legal researcher and from an external point of view, we can infer from the practices employed inside Drug Courts. This brief analysis will try to offer some remarks to the current debate on addiction which needs to be investigated in order to influence access to treatment, the stigma associated with addiction and the unsolvable question *whether* and *to what extent* we can consider addicted individuals responsible for their action and for their behaviour.

Our assumption is that, at least in theory, within the realm of criminal law, individual responsibility is a kind of accountability strictly and deeply anchored to the commission of a fact; nevertheless, the functional link between the illicit fact and the author is taking into account by the recognition that determined psychological and psychophysical coefficients affect the degree and the extent to which a person is considered legally responsible. Within this precise recognition, TJ can be deserving since a sort of “personalization” of responsibility is taking into account by the legal system and inside every criminal trial. In this sense, the use of psychological science is helpful in order to determine when, for example, the degree of incapacity of a person with psychotic decompensation, or with a severe volitional impairment, to commit a certain act matters to address responsibility. Problems concerning the individual degree of capacity and incapacity are surely linked with the discourse on *mental health law* from which TJ has stemmed and further developed. But since our focus is directed to a “border-line case” such as that of drug addiction, the same use of psychological science should be deepened. Defining it border-line case means to recognize that the debate on addiction, seen from a legal perspective, is endless and controversial. And TJ fails in telling us something crucial on it because, notwithstanding the awareness that addiction constitutes a “problem”, it does not tell us conceptually how it can be characterized. From a legal point of view, interpreting and studying a social phenomenon that affects policy choices and judicial activity means to understand an empirical movement that deeply involves the use of categories, paradigms and concepts belonging to the criminal law. Even if, in our case, the pragmatic leading revolutionary movement of Drug Courts has been resting on the TJ premises and knowledges, my intent is to fragment and to probe categories belonging to the language of therapeutic judges and supporters, sometimes taken for granted or even underestimated by the same. Adding that it is appropriate to evaluate how models and categories belonged to the realm of psychological and behavioural sciences are used by Drug Courts to enhance a well-being oriented jurisprudence, considering the fact that not all the categories shared and fostered by Drug Courts can receive

a complete and unquestionable recognition by other sciences. Besides that, categories developed and studied by sciences are not adequately addressed by therapeutic courts.

A *prima facie*, from a criminal policing point of view, TJ can be observed in two ways. The choice to *treat* people for their conduct should mean to admit that, either *problems* (as addiction) are disease states (or sickness) over which people have no control, – and around which the law would detach without interfere by applying its general principle, so permitting a *medical or para-medical* intervention –, or instead that the solution of problems as addiction falls beyond the limits of a serious punishable event caused by the “illegal” conduct. Whether in the first case, we might look at the therapeutic approach as *the instrument* to be followed by the judge as the leading character judging inside a no-more-definable-court. Drug courts, in this case, would endorse the peculiarity of the procedures by saying that these institutions are not courts at all, but diversion-to-treatment programs: the defendants are supervised through regular quasi-judicial status hearings, the drug court judge enters into a dialogue with each defendant about his progress in the treatment/rehabilitation program and so on¹⁶.

Instead, the second manner of thinking would arrive to conceive the therapeutic intervention as an ultimate device to implement, through legal means, the idea that what deserves disapproval is *just* a certain status (or personal condition) and not the event or the action correlated with it. In this case, the law should not detach from the opportunity to punish, but it would create patterns of blameworthiness by telling us that even if the commission of certain event, associated with the conduct, is unimportant, the subject is *legally responsible* for his status of addicted. The judge, put in this way, might represent the institutional character that creates and yields the moral subjectivity of the people before the court modeling the right conduct to follow further.

In other words, it is not clear at all if problems addressed by therapeutic courts are seen and deemed as diseases, crimes, or something else. If addiction is a disease¹⁷, an appropriate contribution could be that of investing and increasing treatment and cure in communities. While, if addiction has to be regarded as crime *per se*, the mere status of addicted risks to be associated with an illegal paradigm.

Regarding more specifically *the problem of addiction*, as put in emphasis by some authors¹⁸, there are at least two ways by which to understand, from a legal point of view, the distinctive courtroom practice employed by Drug Courts and therapeutic judges.

One regards drug court offender as incipient addicts as having a non-voluntary and irrational craving for their abuse, needing treatment and cure; the other evaluates drug offenders as enough rational to accept norms that promote a law-abiding behaviour.

The first alternative is amenable to be categorized as the explication of the so called *disease model* of addiction which claims that addiction is a sort of a biological,

¹⁶ Boldt R. (1998), “Rehabilitative Punishment and the Drug Treatment Court Movement”, *Washington U.L.Q.*, 76.

¹⁷ Leshner A.I. (1997), “Addiction Is a Brain Disease, and It Matters”, *Science*, 278.

¹⁸ See, among others, Miller E.J. (2004).

or psychological propensity to crave drugs. This model is favored by many judicial supporters of TJ. Here, treatment consists in isolating the person and modifying his behaviour by a determined training.

The other alternative assumes that addicts have the choice to weigh the *benefits* of their actions against the potential *consequences* of those actions. Even if they do not practically do it, addicts are considered as people not facing a disease or supporting a strong pathological condition until the point that they are *limited* to overcome the *choice* of facing the craving.

Basically, as it has been observed, Drug Courts seem to follow a model of responsibility that does not negate the first alternative, but at the same time does not want to renounce to the second one. Even if we can recognize that moral and legal accountability is not in general an “all-or-nothing” matter, what seems certain among Drug Courts and TJ is a lacking of a coherent thought on the understanding of addiction. For example, addicts are treated as *clients* in need for cure through medical lens, while the symptoms of their addiction are addressed through a penal one. More deeply, whether the addict is considered as not fully responsible for own drug abuse, the same person has the capacity to respond properly to the whole system of rewards and sanctions arranged by Drug Courts, doing this by voluntary choice. Adding that TJ continuously contributes to remark how the phenomenon of addiction requires a problem-solving approach: the solution to the problem is represented by a mixture of activities held by a psychologist-judge combined with the subscription of a behavioural contract. However, above all, TJ supporters in my opinion fail in grounding addiction on a uncritical acceptance of the disease model.

Thus, these evident and unsolved dichotomies require to be investigate by analyzing the different models of addiction proposed until now, to understand how TJ through Drug Courts can accurately foster its contribution to criminal law and criminal policy choices using psychological research.

At this proposal, many studies have observed how one the most successful outcome enhanced by drug courts, according to therapeutic principles, seems to require clients to adopt a “particular point of view”: the *disease model* of addiction. This means that the defendant’s willingness to admit that his (ab)use of drug is a disease is the parameter on which compliance is often measured. The first remarkable consequence is that a “denial”, *i.e.* any kind of resistance to that model, is seen as a form of refusal from which the defendant should detach, to permit a complete embracing of the training program and the recognition of his addiction as a disease. Secondly, the treatment model employed by drug courts has as central goal that of encouraging the offender to *realize* that the program is designed for his own benefit, through the employment of a courtroom practice based on a therapeutic approach. This courtroom practice can be evaluated and understood – from a legal point of view – stressing some remarks belonged to the realm of legal responsibility. These considerations are crucial, because we

cannot legally explain criminal conduct using a problem-solving approach without addressing the issue in terms of responsibility¹⁹.

Adding that “one point at which science meets responsibility is in the study of addiction”²⁰, the fundamental question is *whether* and *how* science (in our case psychology, through TJ) throws light on the problem of responsibility. Thus, the very Therapeutic Jurisprudence should develop a coherent and organic way of approaching problem-solving courts, elaborating some remarks on the part of individual responsibility and accountability. Doing so, it would mean sharing the idea that TJ as an interdisciplinary study could be viewed as a more reliable contribution to criminal law issues.

I will focus on the matter of addiction as a starting point to capture some of the elements that have not received a proper elaboration among Therapeutic Jurisprudence supporters.

3. The Problem of Addiction

It seems obvious that there are different and controversial philosophical/conceptual explanations of addiction; all cover various viewpoints. Using the research developed by Michael Louis Corrado, we can identify four types – or models – of addiction: a rational addiction (the person behaves in order to maximize his pleasure to the craving); addiction as duress (the person behaves following rational patterns trying to minimize pain response to craving); addiction as distortion (the person behaves irrationally and with a sort of distortion of his own interests); addiction as defect of the will/addiction as disease (the person behaves without having the power to behave otherwise)²¹.

All these models have been supported using different argumentations. It is not uncontroversial if all these kinds of “addictions” are alternatives choices, or continuing phases of a same pathway. It is not even clear how this conceptual distinction compromise Drug Courts practices. What is surely interesting is that these definitions of addiction focus precisely on the issue of voluntary control and of rational behaviour.

So, we might begin asking whether among Drug Courts offenders are regarded as having a non-voluntary and irrational craving for their drug of choice. In few words, if Drug Courts adhere and share a disease model of addiction. In this sense, addiction might have seen as a biological or psychological susceptibility to crave drug which never decreases, but rather requires a constant vigilance to remain under the own addict’s control²². In this case, it would be noticed, the propensity to use drugs might drive the person into an overwhelming and overpowering desire termed craving.

¹⁹ Cotterrell R. (1998), “Why Must Legal Ideas Be Interpreted Sociologically?”, *Journal of Law and Society*, 25(2).

²⁰ Corrado M.L., (2006), “Behavioural Economics, Neurophysiology, Addiction and the Law”, *UNC Legal Studies Research Paper*, No. 892007.

²¹ Corrado M.L. (1999), “Addiction and Responsibility: An Introduction”, *Law and Philosophy*, 18.

²² See Fingarette H. (1975), “Addiction and Criminal Responsibility”, *Yale Law Journal*, 84.

In general, it is said that addiction is a disease because it has a genetic basis. The influence of genes into one's activity may deeply affect the voluntariness of it. However, the major claim to this assertion is that there are a lot of voluntary activities that have a genetic basis. So, what is fundamental to understand is whether genetic differences play a role in voluntary activities.

Some of the research of the last twenty years assert that addiction should be grouped with such disease as Alzheimer's, hypertension, Type 2 diabetes, schizophrenia, asthma, arthritis and even cancer and heart disease²³. Except of these arguments, as we have said, one of the most important claims of the disease interpretation of addiction is that it has a genetic basis. But even if genes influence behaviour, they do not preclude choice, since "we inherit genes [but] we do not inherit behaviours"²⁴. Whether the symptoms of the disease are mechanistic consequences of genetically-driven pathological brain anatomy²⁵ over which the person loses progressively control, once the pathological dis-functioning has been adjusted by treatment, even the "social problem" of the addicted is fixed. Under this model, the isolation of the person and the modification of the behaviour by a determined process of training is the *preferred* choice in order to obtain a successful outcome (the self-liberation from disease).

So, notwithstanding the fact that the nature of addiction has been framed as a biological issue, the biological data have not helped to solve the problem of definition, because in general the criteria for deciding whether an activity is voluntary are behavioural, not genetic. It is fundamental to remember that the differentiation between voluntary and involuntary acts is crucial in law: judicial systems distinguish between voluntary and involuntary acts and, in general, individuals are considered responsible only for those acts that they freely choose and should not be blamed for those that are compelled to commit. But the phenomenon of addiction represents one of those extremely controversial issue upon which both science and law admit their difficulty to arrive to grasp a point of clear understanding. The disease model is just one of the possibility to explain the phenomenon.

Yet, this model has not received a complete acceptance by TJ supporters, even if it would seem contradictory the refusal of such, whether the treatment of the person before the court is considered the therapeutic response to obtain and enhance, at least inside Drug Courts. Nonetheless, therapeutic approach is often associated with the 12-step model of addiction (the training more used by drug courts). The addicted is supposed to conform to a particular model of addiction²⁶, *i.e.* one that need treatment because the person before the courts is ill, not enough capable to understand properly the consequences of his previous behaviour.

²³ See Leshner A.I. (1997); McLellen A.T., D.C. Lewis, C.P. O'Brien, H.D. Kleber (2000), "Drug Dependence, a Chronic Medical Illness: Implications for treatment, insurance, and outcome evaluation", *JAMA: The Journal of the American Medical Association*, 284.

²⁴ Heyman G.M. (2009), *Addiction: a disorder of choice*, Harvard University Press, Harvard.

²⁵ Morse S.J. (2006), "Addiction, Genetics and Criminal Responsibility", *Law and Contemporary Problems*, 69.

²⁶ Miller E.J. (2009), "Drug, Courts and New Penology", *Stanford Law and Policy Review*, 20.

The most important critic that the disease model has received is the fact it risks to identify every kind and every degree of addiction as an illness. But the identification of addiction as an illness would require cure and treatment inside those structures thought to provide help and rehabilitation, without operating with an informal, but however criminal system of sanctions and rewards.

Addiction has been analyzed even as a form of “weakness of the will” or *akrasia*²⁷. Basically, a distortion, as Corrado points out. The “weakness of the will interpretation” of addiction would imply that, even if one acts rationally and knows perfectly what is doing, the person fails to guide his behaviour aligning his own reason with his own desires. According to this thought, there would be a continuous tension between what the addict *ought* to do and what he *desires* to do. This overwhelmed contrast is considered as the main cause of the possible commission of a certain action *against* own will. Thus, it has been said that the addict’s craving is not subject to rational control, but derives from a inner and congenital defect that inhibit him of acting following his “higher-order rational desire for sobriety”²⁸.

By stressing the role of desire in deliberative agency, however, we can see how even the most intense research of pleasure (as drug seeking might be for an addict) would presumably not deprive the person of the possibility to evaluate the “normative parameters” of a certain situation. Basically, it might be that an intense and uncontrollable impulse would stem a sort of impairment of our capacity to weigh normative account “accurately and judiciously”²⁹.

The emphasis put of the non-alignment between desires and reasons adheres to the idea that, at least theoretically, drug seeking and drug taking are also associated with a series of voluntary acts that may require planning responses to a certain condition. The impairment of volition as symptom of a moral weakness might be seen as one of the main justification to enhance treatment and rehabilitation directly sponsoring it by therapeutic judges, as first and ultimate moralizers against a wrongdoer behaviour.

It is even said that in general, an “impairment of volition” might create an “hard choice” situation not controllable by the person. Whether the recognition of this kind of impairment of our volitional powers does not mean to associate it with total incapacitation, might we talk about “involuntary behaviour”? Basically, the capacity to choose following and respecting our “evaluative beliefs”³⁰ can be at stake, notwithstanding the presence of psychological states that try to direct our attention and our action away from the objects of our belief. Put in this way, we can re-think of addiction as an “impairment of our volitional powers of reflective self-control”³¹.

Adding that the degree of difficulty to perform a correct exercise of power of deliberative agency might be considerably higher in the presence of persistence impulse, or desire for drug use than in other situations, it is maybe correct to categorize addic-

²⁷ See Wallace J.R. (1999), “Addiction as Defect of the Will: Some Philosophical Reflections”, *Law and Philosophy*, 18.

²⁸ See Miller E.J. (2009).

²⁹ See Wallace J.R. (1999).

³⁰ Wallace J.R. (1999).

³¹ Wallace J.R. (1999).

tion as a weak disease under a not-always-easy control of the person. The kind of impairment experienced by the individual might be amenable to be associated with a losing of control on behavioural conduct, due to the result of “psychological uncontrollable forces”. The problem is whether these psychological forces are deemed relevant as the basis for understanding addiction as a loss of control.

This manner of thinking is not far from the definition that United States Code gives of addiction: the addict is someone who has *lost* the power of self-control on his behaviour³². By acquiring that the individual has lost something that he previous had, there is an indirect recognition that the individual might lack alignment of his reason with his desire entails addiction. In other words, addict is driven by an overwhelming and overpowering desire termed craving which tends to make loosing control over the action performed. However, the law, up to now, has not acknowledged any category amenable to a sort of *volitional defect* in terms of lack of control in addition to that of defect of rationality.

Thus, is it addiction simply a *matter of control*, or is it not? Looking how US courts had previously regarded the issue in terms of the conduct of the addicted person, we can observe how the criteria used by the criminal apparatus to ascertain criminal responsibility have been entirely behavioural. Any person – even not necessarily an addict – allegedly committing a misdemeanor or a felony is not ascribable in terms of responsibility, if the person is *incapable of rationality* or *compelled to an “hard choice”* situation. It is important to stress how these two normative criteria have been the guides to understand even the phenomenon of addiction in prosecutions, in term of excusing condition. These two parameters of “lack of responsibility” must be regarded as exception to the general rule.

Adding that offenders with impulse disorders, or other conditions that impair volition, have not been recognized as a defense in trials; the same is for people who have claimed to have committed offenses because their will was overcome by “uncontrollable emotions and pressures”.

For example in *United States v. Lyons*³³, the question was whether addiction might constitute the basis for an *insanity plea*, the court stated that “evidence of *mere* narcotics *addiction*, standing alone and *without* other physiological and psychological involvement, raises no issue of such a mental defect or disease as can serve as the basis for insanity defense.” In *State v. Herrera*³⁴, the court held that “evidence of drug dependency alone will not be enough evidence of a ‘mental disease’ or ‘defect’ to justify the giving of a defendant’s mental disease or defect instruction”. In particular the Court said that “in order to be entitled to such an instruction, further evidence which indicates that the drug dependence has resulted in a mental disease or defect – evidence beyond the mere fact of dependence itself – will have to be presented.”

Nowadays, after three decades and more from such trials, “physiological and psychological involvements” seem to have received their recognition considering at least

³² “The term addict means any individual who [...] is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.” 21U.S.C. 802(1) 1994.

³³ 731 F.2d 243, 1984.

³⁴ 594 P.2d 823, 1974.

the practices employed by Drug Courts. Moreover, sentencing as such of the 1970s and the 1980s would have been considered misleading, as we will see, by those who deem addiction either as a physiological, or as a psycho-biological illness that causes pervasive changes in brain function and believe that “all abuse of drugs have common effects on a single pathway (mesolimbic reward system) deep with the brain”³⁵.

Notwithstanding the efforts to take into account the psychological issues of individual problems as addiction, TJ alone fails in proposing a uncritical contribution to the matter of drug use and abuse. TJ supporters refuse to recognize the *disease model* of addiction (or any other nuance of it), although sustaining treatment and therapy as main goals to achieve. Addiction is treated as a problem, characterized by a low self-esteem and psychological impairment of the individual before the court. Even the adherence to the model of the moral weakness would require, from TJ supporters, sharing the idea that medical treatment and rehabilitation are devoted to this precise scope, and maybe they would refuse the idea to *punish* the offender inside the criminal justice system.

In my opinion, the mere use of psychological tools does not constitute a valid hold to built an organic and coherent approach to the issue. Especially because TJ adheres to the simple idea that the “identification, assessment, and communication of emotions are central to the change process that distinguishes the drug court program”³⁶, the matter of addiction *per se* does not receive a deep and complete analysis. This lack of theoretical grounding might be used against TJ itself to depict it, through the words of some authors, as a mere theory of *folk psychology*. Whereas the *desiderata* of TJ relies solely on the role of emotions, feelings and other behavioural attitudes, deemed not accurately evaluated by the legal system, TJ would develop a deep analysis on the matter of addiction *per se*, to enhance credibility and reliability. The fact is that TJ forgets to anchor its assumptions, beliefs and constructions on a thorough and exhaustive research on a problem.

The ultimate risk is again the one I have already stressed among the pages of this work: whether TJ gives importance and continue to develop itself on human science tools, it can not but lay on unsure basis, and be considered one mere “folk psychology” theory. At the same time, if it stops to look into *psycho-* languages and issues, it can inevitably lose its attractive, persuasive and fascinating character. Since the legal basis of TJ, taken autonomously, are frail and subjected to be critically dismantled, it might be interesting and deserving of analysis to see *how* therapeutic courts might have obtained a considerable attention incorporating advances in the understanding of responsible behaviour and criminal policing.

To the other side, addiction has been amenable to a different understanding inside Drug Courts. In fact, drug offenders seems being considered as rational and enough susceptible to accept to adhere to law-abiding norms. This does not mean to negate the

³⁵ Leshner A.I. (1997).

³⁶ Nolan J.L. (2003b).

disease model totally: likely, this second option gives a “volitional account” of moral and legal responsibility. So Drug Courts should be read as a criminal law alternative designed to bring addicted people to evaluate compliance with the law by a different and informal system of sanctions and rewards. This understanding might be considered valid and sharable, notwithstanding the fact, as we have already considered in the previous chapters, it is only anchored to psychological and social assumptions. However, it has been considered a valid underpinning – by the same supporters of TJ – together with the model that, more than others, denies and contradicts its claims. I am talking about the model based on the “new” explanation of addiction that the discoveries by neuroscience have developed and enhanced.

It is worth tracing briefly the history of this neuroscientific approach to addiction to see how it has helped or hijacked the practice of Drug Courts and their therapeutic interventions.

We can observe how, in general terms, neuroscientific evidences are proposing to discover and show the mechanistic insights that guide the interpretations of psychological observation and to offer new explanatory framework for thought, and behaviour³⁷. In the issue of drug use and abuse, among other things, neuroscience offers itself as a guide to acknowledge whether and to what extent we can refer to addiction as a disease. Moreover, it tries to undermine the concept of responsibility by using as a filter that of *voluntariness*.

Put in brief, to one side, the neural circuits stimulated by using addictive drugs have started to be studied. This kind of discoveries have entailed the new search for pharmacological treatment. To the other side, imaging techniques, as fMRI³⁸, have tried to show the effects of psychoactive drugs on the brain. Consequently, as I have already remarked, addiction has come to be understood as a *chronic* disease similar to other chronic diseases which are characterized by intermittent remission and relapse.

Dr. Alan Leshner, chief executive officer of the American Association for the Advancement of Science, is one of the proponent of the view of addiction as a phenomenon that entails a change in brain physiology, no matter what substance is involved. He points out how “the addicted brain is significantly different from the non-addictive brain”³⁹, hypothetically assuming that alterations in brain structure and function are what make it a brain disease. He believes that the addicted person “moves from a *state* where drug use is voluntary and controlled to one where drug craving, seeking, and use are no longer under the same kind of voluntary control”⁴⁰. However, Leshner continues,

³⁷ Hyman S.E. (2007), “The Neurobiology of Addiction: Implications for Voluntary Control of Behaviour”, *American Journal of Bioethics*, 7(1).

³⁸ FMRI, functional magnetic resonance imaging is one of the most prominent tool of neuroscience. “Commonly called brain scanning, fMRI examination holds out the possibility of being able to determine which parts of the brain perform which cognitive tasks” see Schauer F. (2009), “Can bad science be good evidence? Neuroscience, Lie Detection and Beyond”, *Cornell Law Review*, 95.

³⁹ Schauer F. (2009).

⁴⁰ See Qureshi N.A., Y.S. Al-Ghamdy, Al-Habeeb T.A (2000), “Drug Addiction: a general review”, *Eastern Medical Health Journal*, 6; O’Brien C. (2007), “Physician’s Approach to Treating Addiction”, *Hospital practice: A Special Report*.

the exact mechanisms involved in this shift are not known⁴¹. But, notwithstanding that these precise devices are not known yet, Leshner states that a simple description of addiction as symptom of a *moral weakness* should be discarded considering the whole scientific evidence enhanced by neurophysiology.

In addition, what science tries to remark and discover are the various degrees of *voluntariness* that people face when they pass from the status of “drug user” to that of “drug addicted”. As Dr. Leshner has noticed, the difference of the neuronal circuits between an addict’s brain and a nonaddict’s one, permits us “to see the addict as someone whose brain has been *altered* fundamentally by drugs”⁴². These kind of empirical data are supposed to undermine and hijacked the concepts of voluntariness by showing that addicted people can not exercise *control* over their action voluntarily. In sum, by trying to demonstrate that behaviour – the conduct of the person – is determined by own neurological brain states, neuroscientists propose to reveal the “mechanical nature of human action” and the “when”, “where” and “how” of the “mechanical processes that cause behaviour”⁴³.

The characterization of addiction as a moral weakness, but especially as a brain disease, is motivated by the fundamental question to understand whether and to what extent addicted individuals can be considered responsible for their actions and, as we have seen, to what extent addiction focuses on the matter of control. Even if, at least in Drug Courts, the eligibility criteria required to be part of the therapeutic program is often the commission of an illegal act related to drug use or possession – not associated with a violent felony or misdemeanor –, it would be necessary to remember that the particular perspective by which the person before the court has to declared own “condition”, is that of “addicted”. This means that *addiction* is considered the prerequisite to the functioning of Drug Courts. However, empirical activities of therapeutic judges, to be taken seriously, should be founded on a considerable and in-depth analysis of addicted behaviour. Yet, TJ does not pretend to explain either conceptually the matter of addiction, or scientifically the effects on drugs on the individuals, sustaining that a systems of social sanctions and rewards, by a real behavioural contract, is the best instrument to evaluate the functioning of the self-liberation from drugs.

Notwithstanding this *post-factum* approach of Drug Courts, neuroscience is supposed to add a new element. It seems to say to look beyond the mere psychological issues, by understanding how control of behaviour is *anchored into* the brain functions. To demonstrate the validity of this assertion, some neuroscientists have stated that, among other things, a common denominator in the brain of addicted persons is the disease and malfunctioning of the dopamine system⁴⁴. Dopamine is released from neurons with cell bodies in the ventral tegmental area (VTA) and substantia nigra within the

⁴¹ O’Brien C. (2007), in particular: “it is not clear whether that change in state reflects a relatively precipitous change in a single mechanism or multiple mechanisms acting in concert, or whether the shift to addiction represents the sum of more gradual neuro-adaptations”.

⁴² Leshner A.I. (1997).

⁴³ See Greene J., J. Cohen (2004), “For Law, Neuroscience Changes Nothing and Everything”, in Zeki S., O.R. Goodenough, *Law and the brain*, Oxford University Press, Oxford.

⁴⁴ See Goodenough O.R., M. Tucker (2010), “Law and Cognitive Neuroscience”, *Annual Review of Law and Social Sciences*, 6.

mid-brain. In particular these neurons, by projecting through the forebrain, can influence those circuits delegated to be involved in reward-related learning⁴⁵. Basically, the dopamine system is the one that control the production of stimulus associated with pleasure (and thus, even the pleasure associated with drug consumption) and activate behavioural strategies to reach relevant goals (assigning values and “updating” goal representations), but it is also the one which is deeply connected with perception of reward and learning.

Since “the major substrates of persistent compulsive drug use are hypothesized to be molecular and cellular mechanisms that underlie long-term associative memories in several forebrain circuits (involving the ventral and dorsal striatum and prefrontal cortex) that receive input from midbrain dopamine neurons”⁴⁶, the abuse of drugs and addiction might steer the systems by which we learn *what is good to do*⁴⁷.

Is this announcement going to challenge the whole construction of Drug Court practices by which addicted persons are undergone? If TJ wants to give a chance to neuroscientific discoveries, it should reformulate its underpinnings of sanctions and rewards as well, dealt with addicted behaviour. The system of rewards and sanctions on which therapeutic courts anchor their techniques, designed to restructure the addict’s ordering of preferences, is intended to fail, considering the new advances that neuroscience has devised and launched. However most of the research emphasize how neuroscience can not but help to increase the effectiveness and functioning of Drug Courts⁴⁸. What we need to see is if neurolaw can offer a valid underpinning to anchor and recognize legal responsibility.

4. Conclusive Remarks

The choice between the disease and the “volitional” models of addiction has enormous significance for the practices of Drug Courts and, in general for the criminal law. If drug use can be categorized as a behavioural part of a disease, it should not be sanctioned. Instead, if drug use is volitional, the offender ought to be punished since the offender has to be viewed as a moral autonomous and responsible being. What seems certain is that progress in neuroscience have tried, and still continue, to put light on the neural basis of addiction, aiming to reinforce the argument based on “not-at-all-controllable-compulsion” caused by drugs abuse. However, although compulsion and craving are determined either by a “volitional impairment” or by an “irresistible impulse”, we have to admit that science has not yet connected the *links* between brain and behaviour, between neuronal changes and the phenomenon of craving, compulsion or whatsoever action committed by the addicted person. Even accepting the model by which addicted people might wrongly evaluate *what is good to do*, at least during the

⁴⁵ Hyman S.E. (2007).

⁴⁶ Hyman S. *et al.* (2006), “Neural mechanisms of Addiction: the role of reward-related learning and memory”, *Annual Review of Neuroscience*, 29.

⁴⁷ Goodenough O.R., M. Tucker (2010).

⁴⁸ Goodenough O.R., M. Tucker (2010).

moment in which they do not assume drugs, they are deemed as capable of recognize the *good reasons* of their choices.

Yet, what research still misses is the demonstration that the changes in neuronal connectivity are *causally* involved in addicted-related behaviours. Even if this causal mechanism would be displayed, the fact that the biological/physiological mechanisms behind and beyond the addicted control may *cause* a person being more predisposed to commit a determined act (seeking for drugs, or committing a crime to procure money to buy drugs) are not capable of altering or threatening the way by which the law as a system see the *individual* in the end. The wrongdoer is, before everything, an agent and not a mechanistic entity caused by synapses and altered neuro-connectors.

In criminal law, the key postulate of the rule of law is that every person over a certain age is perceived to have the capability to obey the commands of the law. A very narrow exception has traditionally been recognized for people with mental illness who lack the capacity to understand and appreciate the moral significance of their conduct. And it is remarkable to stress how the very beginning of TJ studying approach has been launched exactly by looking at mental health law issues. However, in the United States, some states have expanded the cases of *severe volitional impairments*, causing several controversial debates. Adding that, in general, the criminal law has always been resistant to excusing people who claim to have committed offenses because their will was overwhelmed by emotions and pressures. Basically addiction has not been recognized as a defense in prosecutions, for having used drugs or for being drunk as example. The law, unless the person does not act or an excusing condition is at stake, sees persons as agents possessing moral and legal responsibility. The problem is that, being compulsion and craving intentionally behavioural states, scientific evidences can not explain how not-measurable capacity to control drug use or to manage strong desire for pleasure might constitute excusing condition, or produce sufficiently irrationality on an hard-choice situation for example.

Moreover, both the *disease model* and the *moral weakness* one have been strongly contested, on the issue that scientifically the validity of these models have neither been reached nor accepted by the whole scientific experts. In addition, both the two models do not take into account the behavioural and contextual factors of addiction⁴⁹. Basically, the distortion model and the disease one lays oddly with the voluntary component that law, as a system, has created on behavioural conduct.

At this proposal, regarding the first, it is said that what decisively matters, in analyzing addiction, is the volitional determination of the individual to *give in* to the craving. Then, whether addiction might be explained as a rational immediate response (read: choice) to the craving, the agent might be deemed responsible for his choice to take drugs. Doing to the fact that a mistaken evaluation can not be considered an irrational one, how differently the criminal law should regard those individuals who are not able to *better* evaluate the relevance of their own interests?

⁴⁹ In details, Richard J. Bonnie has stressed how behavioural factors play a more substantial role in addiction than in Alzheimer's disease, Parkinson disease, or epilepsy or even schizophrenia.

Regarding the disease model and the genetic/neural basis of addiction, it is remarked how the mere idea that genes – or neurons – influence a determined activity is not sufficient to hold that a determined action can not be voluntary. In addition, it is said that “a genetic basis for addiction does not automatically mean that addicts are «compulsive, involuntary» drug users”⁵⁰. Brain functioning changes is a logical necessity as well as an experimental fact. But drugs change behaviour, mood, and thought. The addicted is obsessed and attracted by the pleasure associated with drug use: basically, he is governed by the consequences linked with the drug assumption. He voluntarily chooses to use drugs in a self-destructive manner.

There is good material to believe at least that most of addicted are responsible for seeking and using drugs, correlated to a certain conduct or behaviour *now* ascribable in terms of criminal activity at least in US criminal system.

However, I need to recognize that the *disease model* – uncritically accepted by TJ, implicitly practiced by Drug Courts, scientifically acclaimed by neuroscience – does not and can not fully explain some of the criminal law elements concerning addiction. Not simply because law has its own ways of interpreting the world, by determining what is to count as *truth* (that is, offering a correct understanding or appropriate and reliable knowledge for specifically legal purposes)⁵¹, but more specifically because some of the *evaluative standards* used by law pretend to be based on law’s purposes and law’s structure⁵². TJ, as an interdisciplinary approach to the law, but moreover as a theory that tries to solve the whole problem of the individual before the court, should accept a clear model of addiction, trying to use legal categories, in order to be more reliable in the academic field of legal studies and in order to enhance effective practices of addiction-solving-courts based on unambiguous assumptions and outcomes.

In conclusion, from neuroscience, TJ might accept the disease model of addiction in a critical manner. However, doing so, it would mean to admit for TJ that what addicted people really deserve are cure and rehabilitation in communities within real treatment institutions.

By refusing the disease model, notwithstanding the enhancement of treatment in courts, the risk for TJ and Drug Courts is that of associating to addicted people an illegal status, regardless of the crime committed by those people. Finally, indirectly and maybe unconsciously, Therapeutic Jurisprudence would turn in therapeutic criminalization abandoning principles of criminal responsibility.

⁵⁰ Heyman G.M. (2009).

⁵¹ Cotterrell R. (1998).

⁵² Schauer F. (2009).

References

- Bianchi H. (1994). *Justice as a Sanctuary: towards a new system of crime control*. Indiana University Press, Bloomington.
- Boldt R. (1998). "Rehabilitative Punishment and the Drug Treatment Court Movement". *Washington U.L.Q.*, 76.
- Corrado M.L. (1999). "Addiction and Responsibility: An Introduction". *Law and Philosophy*, 18.
- Corrado M.L. (2006). "Behavioural Economics, Neurophysiology, Addiction and the Law". *UNC Legal Studies Research Paper*, No. 892007.
- Cotterrell R. (1998). "Why Must Legal Ideas Be Interpreted Sociologically?". *Journal of Law and Society*, 25(2).
- Dorf M.C., J.A. Fagan (2003). "Problem-Solving Courts: From Innovation to Institutionalization". *American Criminal Law Review*, 40.
- Fingarette H. (1975). "Addiction and Criminal Responsibility". *Yale Law Journal*, 84.
- Fuellen R., J. Trone (2000). "Do Drug Courts Save Jail and Prison Beds?, report written by the New Vera Institute of Justice, New York 2000". [Online], URL: <<http://www.vera.org/download?file=267/IIB%2BDrug%2BCourts.pdf>>.
- Goldkamp J.S. (2000). "The Drug Court Response: Issues and Implications for Justice Change". *Albany Law Review*, 63.
- Goodenough O.R., M. Tucker (2010). "Law and Cognitive Neuroscience. *Annual Review of Law and Social Sciences*, 6.
- Greene J., J. Cohen (2006). "For Law, Neuroscience Changes Nothing and Everything", in Zeki, S., O. Goodenough. *Law and the brain*. Oxford University Press, Oxford.
- Heyman G.M. (2009). *Addiction: a disorder of choice*. Harvard University Press, Harvard.
- Hyman S.E. (2007). "The Neurobiology of Addiction: Implications for Voluntary Control of Behaviour". *American Journal of Bioethics*, 7(1).
- Hyman S.E., Malenka R.C., Nestler E.J. (2006). "Neural Mechanisms of Addiction: The role of reward-related learning and memory". *Annual Review of Neuroscience*, 29.
- Leshner A.I. (1997). "Addiction Is a Brain Disease, and It Matters". *Science*, 278.
- McLellen A.T., D.C. Lewis, C.P. O'Brien, H.D. Kleber (2000). "Drug Dependence, a Chronic Medical Illness: Implications for treatment, insurance, and outcome evaluation". *JAMA: The Journal of the American Medical Association*, 284.
- Miller E.J. (2004). "Embracing Addiction: Drug Courts and the False Promise of Judicial Interventionism". *Ohio State Law Journal*, 65.
- Miller E.J. (2009). "Drug, Courts and New Penology". *Stanford Law and Policy Review*, 20.
- Morse S.J. (2006). "Addiction, Genetics and Criminal Responsibility". *Law and Contemporary Problems*, 69.
- Nolan J.L. (1998). *The Therapeutic State: Justifying Government at Century's End*. NYUP, New York.
- Nolan J.L. (2003a). "Redefining Criminal Courts: Problem-solving and the meaning of Justice". *American Criminal Law Review*, 40.
- Nolan J.L. (2003b). *Reinventing Justice, The American Drug Court Movement*. Princeton University Press, Princeton.

- O'Brien C. (1997). "Physician's Approach to Treating Addiction". *Hospital Practice: A Special Report*.
- Petrila J. (2000). "Paternalism and the Unrealized Promise: Essays in Therapeutic Jurisprudence", in Qureshi N.A., Y.S. Al-Ghamdy, Al-Habeeb T.A.. "Drug Addiction: a general review", *Eastern Medical Health Journal*, 6.
- Schauer F. (2009). "Can Bad Science be Good Evidence? Neuroscience, Lie Detection and Beyond". *Cornell Law Review*, 95.
- Wallace J.R. (1999). "Addiction as Defect of the Will: Some Philosophical Reflections". *Law and Philosophy*, 18.
- Wexler D.B. (1990). *An Introduction to Therapeutic Jurisprudence*, in Wexler D.B. *Therapeutic Jurisprudence: The Law as a Therapeutic Agent*.
- Wexler D.B. (1992). "Putting Mental Health into Mental Health Law: Therapeutic Jurisprudence". *Law and Human Behaviour*, 16(1).
- Wexler D.B. (2008). *Rehabilitating Lawyers: Principles of therapeutic jurisprudence for criminal law practice*. Carolina Academic Press, Durham.
- Wexler D.B., B. Winick (1991). *Essays in Therapeutic Jurisprudence*.
- Wexler D.B., B. Winick (1996). *Law in a Therapeutic Key: Developments in Therapeutic Jurisprudence*.
- Wexler D.B., B. Winick, D. Stolle (2000). *Practicing Therapeutic Jurisprudence: Law as an Helping Profession*.

Synthetic Biology and Human Rights in Europe: A Comparison between the EU and the Council of Europe Systems, in the Field of Health and Environment

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Abstract: The development of SB arises many legal and ethical issues. This paper analyzes the possible legal implications of use of SB in Europe from the point of view of human rights, especially of the right to health and the right to healthy environment. In the European context SB will meet the system of protection of human rights set forth both by EU law and by the instruments of the Council of Europe (mainly the Oviedo Convention, the European Social Charter and the European Convention of Human Rights). In those two systems human rights may be enforced by the Court of Luxembourg (CJEU) and the Court of Strasbourg (ECtHR). After analyzing the main case law of both courts on the health and the environment, I argue that EU law will not probably interfere with the development of SB, whereas the ECHR and the ECtHR show a perfectly operative system of protection of H.R. which may intersect the journey of SB in the future.

Contents: 1. Introduction - 2. The European Union Relevant Context on the SB and the CJEU Case Law - 2.1. The Charter of Fundamental Rights – 2.2. The precautionary principle and the protection of human health - 2.3. The judicial plan for the protection of human health - 3. The Council of Europe Regulatory Context for SB - 3.1. The Convention on Human Rights and the Biomedicine and its Protocols - 3.2. The European Social Charter and the question of the compulsory jurisdiction of the ECtHR - 3.3. The judicial plan of health and environment under the ECHR system - 4. Conclusion - References.

1. Introduction

The development of SB¹ in the next future can involve many interests that may correspond to human rights². Human dignity, right to life, health, protection of the environment, privacy, the self-determination principle and the principle of non-discrimination and so forth are all issues that can be called in question in this field.

All those aspects of the human being may be involved by SB in multiple ways. The use of SB in medicine could involve both health and the life of patients. Think about the engineering of synthetic cells in order to produce biodrugs, antibodies³, or about the creation of biosensors and biocomputers programmed to detect and cure diseases in the presence of specific biomarkers⁴. Think also about some kind of implantable living battery for a medical device, or beneficial bacterial infections programmed to augment immunity, or finally synth-cells that circulate in the body to extend the human immune system. Health could also be called in question during the stages of production and commercialization of products whenever the protection of consumers and workers is at stake. Environmental issues can be called in question either as a general and objective interest to live in a healthy environment or as a subjective interest to have one's family and private life or one's property free from pollution. In this case the environmental dispersion of synthetic-organisms could create some risk for the human being (i.e. spray containing skin surface bacteria reprogrammed to migrate in the presence of dirt, oil with a view toward seeking and destroying pollutants⁵, etc.). The principle of autonomy may be at risk either as the interest of the consumer to make a free and informed choice in the general market, or as the interest of the patient to express a free and informed consent. Think about the possible use of reprogrammed viruses and bacteria to produce proteins to add to food or about the chance to utilize SB in cosmetics (i.e. spray containing bacteria engineered to eat dead skin or to dissolve keratin in facial hair). In these instances the correct information of the consumers through products labelling is the real issue at hand here. The dignity may be at stake whenever an implication of some SB applications exists for a human being beyond his/her own consent, and

¹ According to the EGE SB seeks “to modify existing organisms by designing and synthesising artificial genes or proteins, metabolic or developmental pathways and complete biological systems in order to understand the basic molecular mechanisms of biological organisms and to perform new and useful functions”. See European Group on Ethics in Science and New Technologies (EGE), Ethics of Synthetic Biology, opinion N. 25, Publications Office of the European Union, Luxembourg, 2010, p. 11.

² In this paper, even though human rights have a double dimension both moral and legal [see Pariotti E. (2008), *I diritti umani. Tra giustizia e ordinamenti giuridici*, UTET Università, Torino, p. 3; Viola F., G. Zaccaria (2001), *Diritto e interpretazione. Lineamenti di teoria dell'interpretazione*, Laterza, Roma-Bari, p. 218], I will consider human rights only as legal rights. In light of this paper, I will give a minimal definition of human rights: human rights are those rights and only those that are recognised by international treaties such as the Universal Declaration of Human Rights (UDHR), the International Covenants of 1966, the European Convention of Human Rights (ECHR) and so on. Their structure implies an individual or a group bearer of a right and a state, as counterpart, which should protect it.

³ Fernandes R., V. Roy, H.C. Wu, W.E. Bentley (2010), “Engineered biological nanofactories trigger quorum sensing response in targeted bacteria”, *Nature Nanotechnology*, pp. 213-217.

⁴ Elbaz J., O. Lioubashevski, F. Wang, F. Remacle, R.D. Levine, I. Willner (2010), “DNA computing circuits using libraries of DNzyme”, *Nature Nanotechnology*, pp. 417-422.

⁵ Shina J., S.J. Reyes, J.P. Gallivan (2010), “Reprogramming bacteria to seek and destroy an herbicide”, *Nature Chemical Biology*, pp. 464-470.

whenever any human being consciously chooses to change his/her way of being, genetic heritage, nature, etc. One should keep in mind that one “possibility so far envisaged to modify the genome of complex organisms, including humans, is via the use of artificial chromosomes” that could find some application in the gene-therapy⁶. The prohibition of discrimination may be in question as the interest of the third world countries not to be discriminated with regard to the diffusion and the free access to the main outcomes of SB, but also as the interest of the individual to freely access to the best cures developed by the research in the field of SB or in the case of the application of SB in human enhancement⁷.

In this paper I will attempt to consider the impact of SB on the human rights law in Europe only with regards to two specific fields: health and the environment. The aim of the research is descriptive in the first moment and, then, normative. As regards to the first moment, the paper intends to produce a mere reconstruction of the normative framework of these two fields under the Council of Europe, with special attention to the jurisprudence of the European Court of Human Rights (ECtHR), and under the European Union, with special attention to the jurisprudence of the Court of Justice of the European Union (CJEU). As regards to the second moment of the research, the paper would like to understand whether the level of protection provided by both normative frameworks of the EU and the Council of Europe can bear the challenges of SB and what differences exist between these two spheres. Instead of the EU system, I will argue that the normative framework of the Council of Europe, thanks to the activity of the Strasbourg Court, has a perfectly operative set of rights (particularly, the right to health and the right to a healthy environment) that could play a role in the future development of emerging technologies, with special regards to SB.

2. The European Union Relevant Context on the SB and the CJEU Case Law

2.1. The Charter of Fundamental Rights

In the framework of the European Union, the CJEU was already adjudicating human rights as general principles of the EU law and the constitutional traditions common to the member states. According to many those rights became “only” more visible with the Charter of Fundamental Rights of the EU⁸. With the entry into force of the Lisbon Treaty⁹ on December 1st 2010, whose Article 6(1) expressly recalls the EU Charter signed in Nice in 2000, the Charter of Fundamental Rights is now legally binding. The Charter is formally recognised by TEU-L but not incorporated in it, giving to that in-

⁶ EGE 2010, 23.

⁷ EGE 2010, 23.

⁸ The Charter of Fundamental Rights of the European Union adopted in Nice on December 7, 2000, adapted at Strasbourg on December 12, 2007.

⁹ The Lisbon Treaty (Treaty of Lisbon amending the Treaty of the European Union and the Treaties establishing the European Community) adopted in Lisbon on December 13, 2007 and entered into force on December 1, 2009.

strument the significance of a constitutional separate document and a per se existence¹⁰. In its Preamble, the Charter places the individual at the heart of the EU activity, and recognises the indivisible, universal values of human dignity, freedom, equality and solidarity. This stresses the importance of the concept of the person inside of the whole architecture of the Charter and now of the EU law. In this respect, Article 1 decrees human dignity as inviolable. The centrality of the individual is preserved also against the development of science and technology in the field of biomedicine and biology. This is the first time that this aspect is explicitly referred to in a binding instrument on human rights. Personal integrity, indeed, is granted in this respect by the fundamental Article 3, preserving informed consent, prohibiting eugenic practices, in particular those aimed at the selection of persons, prohibiting body manufacture for financial gain, prohibiting human reproductive cloning¹¹. The modernity of this normative touch is also expressed in the principle of equality: indeed, Article 21 prohibits any form of discrimination based on the grounds of genetic features. The development of SB application on human beings must take into account this insuperable limit. Another article that could be at stake is Article 8, which protects personal data in the context of medical experimentation. It ensures that bioinformatics data do not escape the control of the individual involved. Finally, the *Charter* recognises freedom of scientific research as a fundamental right. Within the boundaries of the EU law, this should be balanced with other human rights. This is an important point because inside the conventional system of the ECHR, where human rights only exist, this is not possible.

2.2. The precautionary principle and the protection of the human health

Concretely, the use of SB in the context of the EU regulatory framework on human rights, involves the EU on two levels: on the level of the existing regulation of the biotechnology, genetic engineering and food safety; and second, on the one of the CJEU. With regard to the first level, the precautionary principle is brought into question. In the EU law, the precautionary principle is explicitly referred to only regarding environmental protection by Article 191(2) (the past Article 174 TEC) of the *Treaty on the European Union*. Nevertheless, its reach is much wider and it can be used in many applications on the basis of a preliminary scientific assessment for which there are sufficient reasons for being concerned about potentially dangerous effects on the environment, on the health of human beings, as well as on animals and vegetables¹².

¹⁰ Pernice I. (2008), *The Treaty of Lisbon and Fundamental Rights*, in Griller S., J. Ziller (eds.), *The Lisbon Treaty: EU Constitutionalism without a Constitutional Treaty?*, Springer, Wien-New York (<http://www.judicialstudies.unr.edu/JS_Summer09/JSP_Week_1/Pernice%20Fundamental%20>).

¹¹ Colombo R. (2003), *Clonazione umana*, in AA. VV., *Il divieto di clonazione umana nel dibattito internazionale. Aspetti scientifici, etici e giuridici*, Libreria Editrice Vaticana, Città del Vaticano (<http://www.academiaavita.org/template.jsp?sez=Pubblicazioni&pag=testo/clonaz_ossrom/colombo/colombo&lang=italiano>).

¹² Botero M.E. (2005), *Il principio di precauzione e le moderne biotecnologie alla luce degli ultimi sviluppi giurisprudenziali della Corte di giustizia di Lussemburgo e dell'ordinamento della Comunità europea*, in D'Aloia A. (ed.), *Bio-tecnologie e valori costituzionali. Atti del seminario di Parma svoltosi il 19 marzo 2004*, Giappichelli, Torino, p. 142.

In the present “risk society”, the situations in which politicians have to take decisions increases every day. In those situations human rights concerns may arise. In the context of the EU law, health is an important domain of the application of the precautionary principle. The precautionary principle is used for protecting the environment and the human life in a phase where any proof of a “concrete risk” of a potential damage is lacking but there is scientific evidence suggesting that it may exist¹³. The legal community has a wide range of discretion¹⁴, by virtue of its political nature¹⁵. Whenever the precautionary principle is at stake during the stage of risk-managing, it goes with the application of other principles within the EU law¹⁶. Those principles are: the principle of proportionality (the decided measures must be proportional to the chosen level of protection), the principle of non-discrimination (the decided measures must be non-discriminatory), the principle of necessity (the measures must be necessary to achieve the relevant aims), the principle of effectiveness (the measures must be an effective and suitable mean to realise the desired aims), the principle requiring a cost-benefit trade off either in the case of action or in the case of inaction, the principle of review (the measures must be reviewed in light of new scientific data), the principle of the inversion of the burden of proof (the proof of the absence of risk must be heard by the producer) and, finally, the transparency principle (in adopting the measure the public authorities must involve all the stakeholders)¹⁷.

The application of the precautionary principle also involves some Community values such as the value of the primacy of the EU law, the value of a complete communication of the information by the Member State, the value of subsidiarity principle (the political decision must be taken by the lower administrative and political level, which is the closer to the citizens) and so forth.

During the application of the precautionary principle in the field of biotechnology and food safety the Community authorities are those who decide the level of risk that is acceptable for the European society. The Member States can only exercise a “power of control” in the case of new alimentary products, whereas those regularly arriving on the market already in conformity with the Community regulations can be “unsafe”¹⁸. Indeed, in the case of food products produced from, but not containing, genetically modified organisms (and in the next future SB could behold a similar concern), a “simplified procedure” is provided¹⁹. According to this “simplified procedure” a novel product is presumed to be “substantially equivalent” to the existing foods or food ingredients and the producer can only make a notification in which he communicates the information regarding the product. In this case, whenever new information states that the product

¹³ Foster K.R., P. Vecchia, M.H. Repacholi (2000), “Risk Management: The Science and the Precautionary Principle”, *Science*, 288(5468), pp. 971-981.

¹⁴ See European Commission, Communication on the precautionary principle COM/2000/1 def.

¹⁵ Botero M.E. (2005).

¹⁶ Botero M.E. (2005). See also Marino I.M. (2011), *Aspetti propedeutici del principio giuridico di precauzione*, in Guerra G., A. Muratorio, E. Pariotti, M. Piccinni, D. Ruggiu, *Forme di responsabilità, regolazione e nanotecnologie*, Il Mulino, Bologna, pp. 95 ss.

¹⁷ Marino I.M. (2011).

¹⁸ Botero M.E. (2005), p. 158.

¹⁹ Regulation (EC) 258/97 Article 5.

endangers the human health or the environment, with the *simplified procedure* the Member States can restrict or suspend *in extremis* the trade in and the use of the food in question in their territories, after immediately informing the Commission (i.e., the so called “safeguard clause”). After a formal procedure, the Commission shall decide on the validity of the unilateral measures of safeguard and restore a common level of protection inside the EU boundaries. In the end, if the State does not comply with the Commission’s decision, the CJEU will intervene.

Instead, with the “formal procedure” the Commission authorises the introduction of new food products containing genetically modified organisms into the EU market²⁰ so as to give an assessment on their harmlessness for the public health. In this phase of the Commission marketing authorisation, the precautionary principle is engaged and unfolds in three steps: first, the identification of its potential negative effects, second, the evaluation of the available scientific data, and finally, a finding of substantial scientific uncertainty. The European Commission *Communication on the precautionary principle* claims that the Community authorities must be guided by three principles: 1) the decision must be grounded on a complete (as far as possible) scientific evaluation so as to determine the level of scientific uncertainty; 2) any decision (to act or not to act) must be grounded on a prior assessment of its risk and possible consequences in the case the authorities decide not to act; and 3) all parties must participate in a study on the various foreseeable actions as soon as they have a scientific evaluation and the risk assessment²¹.

2.3. The judicial plan for the protection of human health

The analysis of the case law of the CJEU and of the Tribunal of First Instance (TFI) both in the matter of biotechnologies²², and in the matter of health and alimentary safety²³ clearly shows the substantial reliance of the judicial bodies on the technical as-

²⁰ Regulation (EC) 1829/2003 Article 4.

²¹ Botero M.E. (2005).

²² The case law of the CJEU on the biotechnology is: judgement of the Court of 21 March 2000 Association Greenpeace France and others v. Ministère de l’Agriculture et de la Pêche and others, Case C-6/99 European Court reports 2003 Page I-01651; judgement of the Court of 12 June 2003 Eva Glawischning and others v. Bundesminister für soziale Sicherheit und Generationen, Case C-316/01 European Court reports 2003 Page I-5995; judgement of the Court of 20 November 2003 Commission of the European community v. French Republic, Case C-296/01 European Court reports 2003 Page I-13909; judgement of the Court of 27 November 2003 Commission of the European community v. French Republic, Case C-429/01 European Court reports 2003 Page I-14355; judgement of the Court of 9 September 2003 Monsanto Agricoltura Italia SpA and others v. Presidenza del Consiglio dei Ministri and others, Case C-236/01 European Court reports 2003 Page I-08105.

²³ The case law of the CJEU on the protection of the consumers safety and scientific development is: judgement of the Court of 27 April 1993 Case C-375/90 European Court reports 1993 Page I-02055; judgement of the Court of 5 May 1998 UK v. Commission of the European Union, Case C-180/96 European Court reports 1998 Page I-02265 (‘Mad cow disease’); judgement of the Court of 5 May 1998 National Farmers’ Union, Case C-157/96 European Court reports 1998 Page I-02211 (‘Mad cow disease’); judgement of the Court of First Instance of 11 September 1993 Alpha Pharma Inc. v. Council of the European Union Case T-70/99 European Court reports 2002 Page II-03495; judgement of the Court of First Instance of 11 September 2002 Pfizer Animal Health v. Council of the European Union Case T-13/99 European Court reports 2002

assessment and on the application of the precautionary principle made by the Community's authorities²⁴. For exemplum, in the *Alpharma case* the CFI stated that the judicial review cannot substitute its assessment of fact for that of the Community institutions on which the Treaty confers sole responsibility for that duty. Moreover, in the present context of scientific uncertainty to overthrow the technical assessment could be nearly impossible. Thus, with regard to the "simplified procedure", the Community's judges stated that a preventive measure may be taken only if the risk is fully demonstrated by conclusive scientific evidence (*Pfizer Animal Health case*). In the same terms, with regard to the "formal procedure", in the *Greenpeace case* the CJEU ruled that if an application for placing on the market of GMO's has been forwarded to the Commission and no Member State has raised any objection, the competent national authority has an *obligation* to give its written consent (unless any information to the contrary has been communicated by the manufacturer or by any other means). Also with regard to the information for the consumers there exist some difficulties. Indeed, if a product proves unsafe after its marketing and it is retired from the market, there is no chance to obtain this information because it could be liable to impede the free movements of goods (*Eva Glawishning case*). It is notable that the application of the precautionary principle in these matters can be balanced with the other pillars of the EU, first of all the free circulation of goods within the European countries. As we saw, given the scientific uncertainty, the judicial review of the application of the precautionary principle by the Community institutions appears merely "proceduralised". In this way the judicial review avoids analysing the substantial content of EU acts as these should be regarded as an important dimension to actually guarantee human rights. This is particularly true in light of the fact that in those decisions the CJEU addresses not much a subjective health interest as a diffused interest which must be balanced with the Community principle of free circulation of goods. When it comes to political and collective goals of the EU, individual rights are not able to play any important role. From a legal point of view, in the CJEU case law the only rights at stake are the companies' rights to place their products on the European market. Within these rights the Community interest in the free movement of goods takes shape.

To sum up, as regards to the possible development of SB, it is not probable that any inhibiting interference by the EU law and the jurisprudence of CJEU will occur in the near future. This conclusion is due to the fact that in the EU law human rights may be balanced with different values of the EU. Moreover, as health is not handled by CJEU jurisprudence as an individual right, CJEU should first develop health as an au-

Page II-03305; judgement of the Court of First Instance of 21 October 2003 *Solvey Pharmaceuticals v. Council of the European Union* Case T-392/02 European Court reports 2003 Page II-04555; judgement of the Court of 13 November 2003 *Granarolo SpA v. Comune di Bologna* Case C-294/01 European Court reports 2003 Page I-13429; judgement of the Court of 5 February 2004 *Commission of the European community v. French Republic* Case C-24/00 European Court reports 2004 Page I-01277; judgement of the Court of 5 February 2004 *Commission of the European community v. Italian Republic* Case C-270/02 European Court reports 2004 Page I-01559.

²⁴ Giovannetti T. (2005), *Biotechnologie e sicurezza alimentare la tutela della salute del consumatore tra Corte costituzionale e Corte di giustizia della Comunità europea*, in D'Aloia A. (ed.), *Bio-tecnologie e valori costituzionali. Atti del seminario di Parma svoltosi il 19 marzo 2004*, Giappichelli, Torino, p. 336.

onomous concept and then progressively empower it. The CJEU applied the principles of EU law as constitutional traditions common to the member states, but never treated health as an individual right, especially in the field of consumer safety and biotechnologies. For this reasons, it is not probable that the CJEU will begin to handle health as an individual right, nor it is likely that the CJEU will suddenly start to build its semantic content *ex nihilo*.

3. The Council of Europe Regulatory Context for SB

In the context of the Council of Europe instruments, the European Convention of Human Rights (ECHR) and its Court represent the core of the whole architecture. Although various instruments with different legal force can be called in question when developments in science and technology are at issue, the ECHR remains a central and steadfast point. The Oviedo Convention²⁵ and its Protocols²⁶ are other instruments that similarly may not be set aside²⁷.

3.1. The Convention on Human Rights and the Biomedicine and its Protocols

The Oviedo Convention is the main legally binding instrument in international law for the protection of human dignity and integrity of the person regarding the application of biomedicine. It should have been followed by other protocols on the matters of transplantation of human organs and tissues, medical research on human beings and embryos, genetic technology and the study of the human genome, the use of genetic in-

²⁵ The Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) (CETS n. 164) adopted in Oviedo on April 4, 1997 (entered into force on December 1, 1999).

²⁶ The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (CETS n. 168) adopted in Paris on January 12, 1998 (entered into force on March 1, 2001); The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origins (CETS n. 186) adopted in Strasbourg on January 24, 2002 (entered into force on May 1, 2006); The Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Biomedical Research (CETS n. 195) adopted in Strasbourg on January 25, 2005 (entered into force on September 1, 2007); The Additional Protocol to the Convention on Human Rights and Biomedicine concerning the genetic testing for health purposes (CETS n. 203) adopted in Strasbourg on November 11, 2008 (it has not entered into force yet).

²⁷ See also: the European Agreement on the Exchange of Therapeutic Substances of Human Origin; the European Agreement on the Exchange of Tissue-Typing Reagents; the Convention on Unification of Certain Points of Substantive Laws on Patents for Invention; the Convention on Elaboration of a European Pharmacopeia; the Convention on the Protection of the Environment through Criminal Law should also be considered. Consider also some acts of the Parliamentary Assembly: the Recommendation 934 of the Parliamentary Assembly of the Council of Europe on the genetic engineering adopted on January 26, 1982; the Recommendation 1213 of the Parliamentary Assembly of the Council of Europe on the biotechnology and the consequences for the agriculture adopted on May 12, 1993; Recommendation 1425 of the Parliamentary Assembly of the Council of Europe on the biotechnology and the intellectual propriety adopted on September 20, 1999; the Recommendation 1468 of the Parliamentary Assembly of the Council of Europe on the biotechnology adopted on June 29, 2000; the Recommendation 1512 of the Parliamentary Assembly of the Council of Europe on the protection for the human genome by the Council of Europe adopted on April 20, 2001.

formation in ambits other than medical, and artificial procreation²⁸. The aim of the Convention is to protect human dignity from the “misuse of the biology and medicine”²⁹. It is notable that this is the first text of the Council of Europe where the idea of human dignity is mentioned and it is set forth relating the developments in science and technology. Whereas the EU *Charter of Fundamental Rights* recognises freedom of scientific research as a right, the Oviedo Convention does not³⁰. Article 2 of the document of the Council of Europe decrees the primacy of «the interests and welfare of the human being» «over the sole interest of society or science». The wording of this article mentions the *sole* interest of science, so the primacy of the interest and the welfare of the human being are not meant to be as absolute because, merging the interest of science with some other supreme interests (as the protection of public health), some restrictions could be provided. The rights set forth by the Convention may be postponed only for restrictions prescribed by the law and for those which «are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others» (Article 26). Additionally, the Protocol on *biomedical research*³¹ affirms the principle of proportionality of risks and benefits with regards to the scientific research (the risks are not to be disproportionate to prospective benefits). Furthermore, it affirms also the principle of the multidisciplinary examination by scientific and ethical committees on the merit, the aim and the ethical implication of the research (Articles 7, 8 and 9)³².

Both the notion of human being and the notion of person are lacking in the Oviedo Convention. The general belief is that the term “human being” also includes the embryo; instead the term “person”, according to the interpretation of the ECtHR, would include only the persons who are already born³³.

Article 3 of the Oviedo Convention provides for equitable access to health care. Article 4 provides that any intervention in the health field, including research, must be carried out in accordance with the professional obligations and standards (including relevant ethical codes). Article 5 decrees the basic principle of autonomy of the individual and prescribes the free and informed consent to interventions in the health field. Moreover the consent may be withdrawn at any time³⁴.

²⁸ De Salvia C., (2000), “La Convenzione del Consiglio d’Europa sui diritti dell’uomo e la biomedicina”, *I diritti dell’Uomo. Cronache e battaglie*, 11(1-2), pp. 107 ss.

²⁹ See the Preamble of the Oviedo Convention.

³⁰ Compare with Article 2, d of the UNESCO, Universal Declaration on Bioethics and Human Rights, adopted by acclamation by the 33rd session of the General Conference of the UNESCO in October 19, 2005.

³¹ The Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Biomedical Research (CETS n. 195) adopted in Strasbourg on January 25, 2005 (entered into force on September 1, 2007).

³² On the scientific research on human beings see also Articles 3, 4, 5, 6 of the Protocol on biomedical research.

³³ See *X v. United Kingdom* (Appl. 8416/79), decision of the Commission of 13 May 1980, Decision and Reports, 19, pp. 244-254. Compare De Salvia C. (2000), p. 107; Byk, C. (199), *Bioéthique et Convention européenne des droits de l’homme*, in Pettiti L.E, E. Decaux, P.H. Imbert (eds.), *La Convention européenne des droits de l’homme. Commentaire article par article*, Economica, Paris, pp. 101-121.

³⁴ The Protocol on biomedical research, which does not apply to the research on embryos both in vivo and in vitro, reaffirms the principle of free and informed consent (Article 13) and protects diverse persons due to their particular vulnerable position (e.g. person without the capacity to consent, pregnant women, persons in emergency clinical situations, persons deprived of liberty and so forth).

Special attention is given to the issue of genetic biology. Article 11 prohibits any form of discrimination of the person on the grounds of his or her genetic heritage, integrating in this regard Article 14 of the ECHR³⁵. It is notable that, differently from the UNESCO *Declaration on Human Genome*³⁶, the Convention does not contain any declaration of the human genome as the heritage of humanity. The Additional Protocol³⁷ of 1998 prohibits the creation of human beings that are genetically identical to another whether living or dead (Article 1). Article 12 of the Oviedo Convention prohibits any predictive genetic test unless for the sole health purpose or for scientific research linked to health purposes, and subject to appropriate genetic counselling. In this regard, any contract of insurance or of employment cannot include a genetic test. Regarding this matter, a specific Additional Protocol³⁸ exists which indicates that this does not apply to genetic tests on human embryo or foetus and genetic tests for research purposes. The Protocol integrates Article 11 with the prohibition of any stigmatisation of persons or groups on the basis of their genetic characteristics (Article 4). Article 16 of that Protocol defends the privacy of the person integrating both Article 10 of the Oviedo Convention and the basic Article 8 of ECHR which protects private life.

Also, the Oviedo Convention considers the rights of the future generation. Article 13 prescribes that an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aims are not to modify the genome of descendants³⁹. For the Oviedo Convention any enhancing genetic therapy or any therapy directed to human enhancement that modifies the germ line should be viewed as prohibited because such modifications would violate the rights of the persons who inherit this genetic modification⁴⁰. In this regard it should be noted that the technique of medically assisted procreation cannot be allowed for the purpose of selecting the sex of a future child. Finally, an Additional Protocol⁴¹ prohibits human reproductive cloning⁴².

³⁵ See also Article 1 of the above mentioned Protocol on biomedical research which protects «the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms».

³⁶ UNESCO, Universal Declaration on the Human Genome and Human Rights, adopted by the UNESCO General Conference in November 11, 1997 and subsequently endorsed by the United Nations General Assembly in 1998.

³⁷ The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (CETS n. 168) adopted in Paris on January 12, 1998 (entered into force on March 1, 2001).

³⁸ The Additional Protocol to the Convention on Human Rights and Biomedicine concerning the genetic testing for health purposes (CETS n. 203) adopted in Strasbourg on November 11, 2008 (it has not entered into force yet).

³⁹ So Article 13 prohibits the germ-line interventions that, unlike alterations of genes in somatic-cells, which affect only the treated person, would be passed to the next generations, modifying the germ cells (gametes) or early embryos before the stage of differentiation. See on this Andorno R. (2002), "Biomedicine and international human rights law: in search of global consensus", *Bulletin of the World Health Organization*, vol. 80, p. 961.

⁴⁰ Andorno R. (2002).

⁴¹ The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (CETS n. 168) adopted in Paris on January 12, 1998 (entered into force on March 1, 2001).

⁴² The Oviedo Convention prohibits the "reproductive cloning", but not the "therapeutic cloning". In the first case the cloned embryo is transferred to a woman's uterus in the view of having a baby genetically identical to the cell donor. In the second case the embryo's inner mass is harvested and grown in culture in vitro for

Article 21 sets forth the principle that the human body and its parts shall not, as such, give rise to financial gain (as for the donation of organs, tissues, blood). It does not prohibit the sale of pharmaceutical products of human origin (e.g. human blood and its derivatives)⁴³. Article 22 prohibits the storage and use of part of human beings removed in course of an intervention for a purpose other than that for which it was removed (and only with appropriate information and consent procedures).

It is notable that the Additional Protocol *on biomedical research*⁴⁴ also defends the nationals of the States not parties to the ECHR (in particular nationals from Developing Countries). It provides also the right to the confidentiality of personal data and to the accessibility to the information by the persons involved in biomedical research (Articles 25 and 26)⁴⁵.

For what concerns the enforcement of the provisions of the Oviedo Convention, the Secretary General of the Council of Europe determines the application of the Convention, whereas the ECtHR may give “advisory opinions on legal questions concerning interpretation of the text” (Article 29).

3.2. The European Social Charter⁴⁶ and the question of the compulsory jurisdiction of the ECtHR

Whereas the EU *Charter* contains both civil and political rights, as well as economic, social and cultural rights, the ECHR sets forth only civil and political rights. Thus, the right to health and the right to environment, which have a social character, cannot find in that instrument any application. The main problem is that the Strasbourg Court plays a compulsory role only within the ECHR. In all the other conventions of the Council of Europe, there is no compulsory mechanism and the ECtHR does not play any role. Only in the Oviedo Convention the Court plays an interpretative role, notably without any compulsory jurisdiction. This means that the ECtHR cannot apply any norm of the Convention on biomedicine *directly*. But since the civil and political rights can also have economic and social implications, the Court can *indirectly* protect the economic

subsequent derivation of embryonic stem cells in view of therapeutic applications as the cure of Alzheimer’s disease. In this case the human cloned stem cell derives from a human embryo which, if transferred to a uterus, would be able to become a fetus, and then a baby. Here the outcome is not an identical human being, but the destruction of the embryo for therapeutic purpose (Andorno 2002; Colombo 2003).

⁴³ On this see also the European Agreement on the Exchange of Therapeutic Substances of Human Origin (CETS n. 26) adopted in Paris on December 15, 1958 (entered into force on January 1, 1959).

⁴⁴ The Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Biomedical Research (CETS n. 195) adopted in Strasbourg on January 25, 2005 (entered into force on September 1, 2007).

⁴⁵ On this matter see also the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CETS n. 108) adopted in Strasbourg on January 28, 1981 (entered into force on October 10, 1985) and its Additional Protocol Regarding the Supervisory Authorities and Transborder Data Flows, (CETS n. 181) adopted in Strasbourg on November 8, 2001 (entered into force on July 1, 2004).

⁴⁶ The Council of Europe, European Social Charter (ESC) (CETS n. 35), adopted in Turin on October 3, 1961 (entered into force on February 26, 1965) revised in Strasbourg on May 3, 1996 (CETS n. 163) (entered into force on July 1, 1999).

and social aspects of human rights⁴⁷ such as the right to health or the right to environment⁴⁸. With the protection *par ricochet* (indirect) some aspects of the Oviedo Convention and of the other conventions of the Council of Europe (such as ESC) may also find a form of compulsory protection. In this context, the case law of the ECtHR on the right to health⁴⁹ and the right to a healthy environment⁵⁰ can give us an idea of the normative framework that SB could meet.

⁴⁷ See *Airey v. Ireland* (Appl. 6289/73), judgement of 9 October 1979, Series A, No. 32, § 26 “Whilst the Convention sets forth what are essentially civil and political rights, many of them have implications of a social or economic nature”.

⁴⁸ On this see Olivieri F. (2008), “La Carta sociale europea tra enunciazioni dei diritti, meccanismi di controllo e applicazioni delle corti nazionali. La lunga marcia verso l’effettività”, *RDSS. Rivista del diritto della sicurezza sociale*, 8(3), p. 537; Foà S. (1998), *Il fondamento europeo del diritto alla salute. Competenze istituzionali e profili di tutela*, in Gallo C.E., B. Pezzini (eds.), *Profili attuali del diritto alla salute*, Giuffrè, Milano, p. 60; Gitti A. (1998), “La Corte europea dei diritti dell’uomo e la Convenzione sulla biomedicina”, *Rivista internazionale dei diritti dell’uomo*, 11(3), p. 730.

⁴⁹ See *Association X v. The United Kingdom*, (Appl. 7154/75), decision of the Commission of 12 July 1978, Decision and Reports, 14, p. 35; *Brüggemann and Scheuten v. Federal Republic of Germany* (Appl. 6959/75), decision of the Commission of 19 May 1976, Decision and Reports, 5, p. 103; *Guerra and others v. Italy* (App. 14967/89), judgement of 19 February 1998, Reports, 1998-I; *Herczegfalvy v. Austria* (Appl. 10533/83), judgement of 24 September 1992, Series A, No. 244-A; *Hughes c. Royaume-Uni* (requête n° 6040/73) décision du 20 juillet 1973, Collection, 44, pp. 121-123; *Kundsen v. Norway*, (Appl. 11045/84), decision of the Commission of 8 March 1985, Decision and Reports, 42, p. 247; *L.C.B. v. The United Kingdom* (App. 23413/94), judgement of 9 June 1998, Reports, 1998-III; *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement of 26 November 1996, Reports, 1998-III; *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement (revision) of 28 January 2000, Reports of Judgements and Decisions, 2000-I; *Öneryildiz v. Turkey* (App. 48939/99), judgement of 30 November 2004, Reports of Judgement and Decisions, 2004-XII; *Open Door case and Dublin Well Woman v. Ireland* (Appl. 14234/88, 14235/88), judgement of 29 October 1992, Series A, No. 246-A; *Osman v. United Kingdom*, (Appl. 23452/94), judgement of 28 October 1998, Reports of Judgement and Decisions, 1998-VIII; *Roche v. The United Kingdom* (App. 32555/96), judgement of 19 October 2005, Reports of Judgements and Decisions, 2005-IX; *Tysiąc v. Poland* (Appl. 5410/03), judgement of 24 September 2007, selected for publication in Reports of Judgements and Decisions; *X v. Austria* (Appl. 8278/78), decision of the Commission of 13 December 1979, Decision and Reports, 18, p. 157; *X v. Denmark* (Appl. 9974/82), decision of the Commission of 2 March 1983, Decision and Reports, 32, p. 282; *X v. Ireland* (Appl. 6839/74), decision of the Commission of 4 October 1976, Decision and Reports, 7, p. 79; *X v. The United Kingdom* (Appl. 8416/78), decision of the Commission of 13 May 1980, Decision and Reports, 19, p. 244 (also cited as *Paton v. UK*); *Y.F. v. Turkey* (Appl. 24209/94), judgement of 22 July 2003, Reports of Judgements and Decisions, 2003-IX.

⁵⁰ *Arrondelle v. The United Kingdom* (Appl. 7889/77), decision of the Commission of 15 July 1980, Decision and Reports, 19, p. 186; *Athanassoglou and others v. Switzerland* (Appl. 27644/95), judgement of 6 April 2000, Reports of Judgements and Decisions, 2000-IV; *Balmer-Schafroth and others v. Switzerland* (App. 22110/93), judgement of 26 August 1997, Reports, 1997-IV; *Baggs v. The United Kingdom* (Appl. 9310/81), decision of the Commission of 14 October 1985, Decision and Reports, 44, p. 14; *Budayeva and others v. Russia* (Appl. 15339/02, 21116/02, 11673/02 and 15343/02), judgement of 2 November 2006, selected for publication in Reports of Judgements and Decisions; *Fadeyeva v. Russia* (Appl. 55723/00), judgement of 9 June 2005, Reports of Judgements and Decisions, 2005-IV; *Fredin v. Sweden* (Appl. 12033/86), judgement of 18 February 1991, Series A, No. 192; *Giacomelli v. Italy* (Appl. 59909/00), judgement of 2 March 2008, selected for publication in Reports of Judgements and Decisions; *Gounaridis, Iliopoulos et Papapostoulou c. Greece* (requête n° 41207/98), décision du 21 octobre 1998; *Guerra and others v. Italy* (App. 14967/89), judgement of 19 February 1998, Reports, 1998-I; *Hatton and others v. The United Kingdom* (App. 36022/97), judgement of 2 October 2001, Reports of Judgements and Decisions, 2003-VIII; *L.C.B. v. The United Kingdom* (App. 23413/94), judgement of 9 June 1998, Reports, 1998-III; *López Ostrav. Spain* (Appl. 16798/90), judgement of 9 December 1994, Series A, No. 303-C; *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement of 26 November 1996, Reports, 1998-III; *MacGinley and Egan v. United Kingdom* (App. 21825/93 and 23414/94), judgement of 28 January 2000, Reports, 1998-III; *Powell and Rayner v. The United Kingdom* (Appl. 9310/81), judgement of 21 February 1990, Series A,

3.3. The judicial plan of health and environment under the ECHR system

The attention of the Strasbourg Court on the economic and social implications of the civil and political rights has permitted the development of both the right to health and a healthy environment. For exemplum, in the *Open Door case* the ECtHR acknowledged that when the restrictions on the freedom of receiving or imparting information on one's own health (which is protected by the freedom of expression ex Article 10 ECHR) may affect crucial conditions to a person's health and well-being, there exists a violation of the Convention. In the *Öneryildiz case*⁵¹ the ECtHR stated that the State could be judged responsible for dangerous activities managed by private agents (industrial companies), and recalled that the State "must govern the licensing, setting up, operation, security and supervision of the activity and must make it compulsory for all those concerned to take practical measures to ensure the effective protection of citizens whose lives might be endangered by the inherent risks". Among these measures, the right to information (protected by Article 8 ECHR) is very relevant. In the *L.C.B. case*, where the applicant's father was a catering assistant during several British nuclear tests in the Pacific Ocean during the sixties, the ECtHR observed that the lack of the proof of the causal link between the father's exposure to the radiation and the daughter's leukemia may impede the success of the application, but it also held that the State was under the duty to make her parents aware of the existence of a danger of contracting life-threatening disease due to her father's presence in the nuclear tests area. In the main case on experimentation, *Roche v. United Kingdom*⁵², where the applicant, a soldier who participated in chemical experiments between 1953 and 1968 at Chemical and Biological Defence Establishment at Porton Down, and who claimed, in vain, compensation, for the illness related to that exposure, the Court acknowledged that the refusal to provide the requested reports constituted a violation (of the Article 8) of the ECHR.

Notwithstanding some obvious limits (as the lack of decisions on the matter of biotechnology and genetic engineering), medical and chemical experimentation⁵³, positive state obligation for health protection⁵⁴, state responsibility for damages caused by pri-

No. 172; *Spire v. France* (Appl. 13728/88), decision of the Commission of 17 May 1990, Decision and Reports, 65, p. 258; *Surugiu c. Romania* (requête n° 48995/99), arrêt du 20 avril 2004; *Taşkin and others v. Turkey* (Appl. 46117/99), judgement of 10 November 2004, Reports of Judgements and Decisions, 2004-X; *Taura and others v. France* (Appl. 28204/95), decision of the Commission of 4 December 1995, Decision and Reports, 83-B, p. 112; *Zander v. Sweden* (Appl. 14282/88), judgement of 25 November 1993, Series A, No. 279-B; *Zimmerman and Steirner v. Switzerland* (Appl. 8737/79), judgement of 13 July 1983, Series A, No. 66.

⁵¹ *Öneryildiz v. Turkey* (App. 48939/99), judgement of 30 November 2004, Reports of Judgement and Decisions, 2004-XII, par. 90.

⁵² *Roche v. The United Kingdom* (App. 32555/96), judgement of 19 October 2005, Reports of Judgements and Decisions, 2005-IX.

⁵³ See *X v. Austria* (Appl. 8278/78), decision of the Commission of 13 December 1979, Decision and Reports, 18; *Y.F.v. Turkey* (Appl. 24209/94), judgement of 22 July 2003, Reports of Judgements and Decisions, 2003-IX; *X v. Denmark* (Appl. 9974/82), decision of the Commission of 2 March 1983, Decision and Reports, 32; *Herczegfalvy v. Austria*, (Appl. 10533/83), judgement of 24 September 1992, Series A, No. 244-A; *Roche v. The United Kingdom* (App. 32555/96), judgement of 19 October 2005, Reports of Judgements and Decisions, 2005-IX.

⁵⁴ *Tysiąc v. Poland* (Appl. 5410/03), judgement of 24 September 2007, selected for publication in Reports of Judgements and Decisions; *X v. Ireland* (Appl. 6839/74), decision of the Commission of 4 October 1976, Decision and Reports; *Guerra and others v. Italy* (App. 14967/89), judgement of 19 February 1998, Reports,

vate industry⁵⁵, access to health personal data⁵⁶ or public records⁵⁷, protection of workers' health during experimentation⁵⁸, possible development of the equality principle, relevance of scientific uncertainty⁵⁹, individual protection against pollution⁶⁰, the state margin of free appreciation when a public interest is at stake⁶¹, made the right to health and the right to a healthy environment perfectly operative under the ECHR system so that they may interact with the next developments in science and technology that will occur both from the public powers and the private companies. We should also mention the on-going process of Union's accession to the ECHR that could increase the role of the Strasbourg Court under the EU in the future⁶².

4. Conclusion

The analysis of the normative framework of the EU and the Council of Europe leads us to some provisory conclusion. With regards to the two aspects of health and the protection of the environment the mechanism provided in the Council of Europe framework offers better guarantees for individuals. It is to say that the conclusion could be different if we considered some other aspects such as human dignity where the CJEU has a more developed case law, with special regards to the biotechnological field⁶³.

1998-I; *Budayeva and others v. Russia* (Appl. 15339/02, 21116/02, 11673/02 and 15343/02), judgement of 2 November 2006, selected for publication in Reports of Judgements and Decisions.

⁵⁵ *Öneryıldız v. Turkey* (App. 48939/99), judgement of 30 November 2004, Reports of Judgement and Decisions, 2004-XII.

⁵⁶ *Roche v. The United Kingdom* (App. 32555/96), judgement of 19 October 2005, Reports of Judgements and Decisions, 2005-IX.

⁵⁷ *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement of 26 November 1996, Reports, 1998-III.

⁵⁸ *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement of 26 November 1996, Reports, 1998-III and *MacGinley and Egan v. The United Kingdom* (App. 21825/93 and 23414/94), judgement (revision) of 28 January 2000, Reports of Judgements and Decisions, 2000-I; *Osman v. The United Kingdom*, (Appl. 23452/94), judgement of 28 October 1998, Reports of Judgement and Decisions, 1998-VIII; *Tauira and others v. France* (Appl. 28204/95) decision of the Commission of 4 December 1995, Decision and Reports, 83-B.

⁵⁹ *L.C.B. v. The United Kingdom* (App. 23413/94), judgement of 9 June 1998, Reports, 1998-III.

⁶⁰ *Powell and Rayner v. The United Kingdom* (Appl. 9310/81), judgement of 21 February 1990, Series A, No. 172.

⁶¹ *Tauira and others v. France* (Appl. 28204/95) decision of the Commission of 4 December 1995, Decision and Reports, 83-B; *Fredin v. Sweden* (Appl. 12033/86), judgement of 18 February 1991, Series A, No. 192.

⁶² The accession is now a legal obligation thanks to Article 6, paragraph 2 of the Lisbon Treaty.

⁶³ See, for instance, opinion of the Advocate General of 10 March 2011 *Oliver Brüstle v. Greenpeace eV*, Case C-34/10.

References

- Andorno R. (2002). "Biomedicine and International Human Rights Law: in search of global consensus". *Bulletin of the World Health Organization*, 80.
- Ball P. (2005). "Synthetic biology for nanotechnology". *Nanotechnology*, 16.
- Beck U. (1986). *Risikogesellschaft. Auf dem Weg in eine andere Moderne*. Suhrkamp Verlag, Frankfurt am Main.
- Beghè Loreti A. (1998). "Brevi considerazioni sulla protezione giuridica delle informazioni genetiche nel diritto internazionale comunitario". *Rivista internazionale dei diritti dell'uomo*, 11(1).
- Beghè Loreti A. (2001). "Osservatorio sulla bioetica. Bioetica e diritto comunitario: le prospettive dischiuse dalla Carta dei diritti fondamentali dell'Unione Europea". *Rivista internazionale dei diritti dell'uomo. Atti del Seminario internazionale Assistenza umanitaria e diritto internazionale umanitario (Milano, 24 maggio 2000)*, 14(1).
- Beghè Loreti A. (2006). *Normativa internazionale e ricerca biomedica. Conquiste attuali e prospettive future*, in De Dios Vial Carrea J., E. Sgreccia (eds.), *Etica della ricerca biomedica. Per una visione cristiana. Atti della IX Assemblea Generale della Pontificia Accademia Pro Vita (Città del Vaticano, 24-26 febbraio 2003)*. Libreria Editrice Vaticana, Città del Vaticano. [Online], URL: <http://www.academia.org/template.jsp?sez=Publicazioni&pag=testo/et_ricbiom/beghe/beghe&lang=italiano>.
- Beghè Loreti A., L. Marin (1999). "La tutela della persona umana nella sperimentazione clinica dei farmaci e il ruolo dei comitati etici tra regole internazionali di disciplina e normativa italiana". *Rivista internazionale dei diritti dell'uomo. Atti del Seminario internazionale Diritti dell'uomo e profili etnico-religiosi: una prospettiva globale (Milano, 3-4 dicembre 1998)*, 12.
- Blasi A. (1999). "La protezione dei dati personali nella giurisprudenza della Corte europea dei diritti dell'uomo". *Rivista internazionale dei diritti dell'uomo. Atti del Seminario internazionale Diritti dell'uomo e profili etnico-religiosi: una prospettiva globale (Milano, 3-4 dicembre 1998)*, 12.
- Botero M.E. (2005). *Il principio di precauzione e le moderne biotecnologie alla luce degli ultimi sviluppi giurisprudenziali della Corte di giustizia di Lussemburgo e dell'ordinamento della Comunità europea*, in D'Aloia A. (ed.), *Bio-tecnologie e valori costituzionali. Atti del seminario di Parma svoltosi il 19 marzo 2004*. Giappichelli, Torino.
- Brownsword R. (2004). *Techno-Regulation, Human Rights and Human Dignity*, in Brownsword R. (ed.), *Global Governance and the Quest for Justice, vol. IV: Human Rights*. Hart Publishing, Oxford and Portland, Oregon.
- Bultrini A. (2004). *La pluralità dei meccanismi di tutela dei diritti umani in Europa*. Giappichelli, Torino.
- Byk C. (1999). *Bioéthique et Convention européenne des droits de l'homme*, in Pettiti, L.E., E. Decaux, P.H. Imbert (eds.), *La Convention européenne des droits de l'homme. Commentaire article par article*. Economica, Paris.

- Colombo R. (2003). *Clonazione umana*, in AA. VV. *Il divieto di clonazione umana nel dibattito internazionale. Aspetti scientifici, etici e giuridici*. Libreria Editrice Vaticana, Città del Vaticano. [Online], URL: <http://www.academiavita.org/template.jsp?sez=Publicazioni&pag=testo/clonaz_ossrom/colombo/colombo&lang=italiano>.
- De Salvia C. (2000). “La Convenzione del Consiglio d’Europa sui diritti dell’uomo e la biomedicina”. *I diritti dell’Uomo. Cronache e battaglie*, 11.
- De Salvia M. (1997). “Ambiente e Convenzione europea dei diritti dell’uomo”. *Rivista internazionale dei diritti dell’uomo*, 10.
- Del Vecchio A.M. (2001). “Considerazioni sulla tutela dell’ambiente in dimensione internazionale ed in considerazione con la salute umana”. *Rivista internazionale dei diritti dell’uomo Atti del Seminario internazionale Assistenza umanitaria e diritto internazionale umanitario (Milano, 24 maggio 2000)*, 14(1).
- European Group on Ethics in Science and New Technologies (EGE) (2010). *Ethics of Synthetic Biology, opinion N. 25*. Publications Office of the European Union, Luxemburg.
- Elbaz J., O. Lioubashevski, F. Wang, F. Rémacle, R.D. Levine, I. Willer (2010). “DNA computing circuits using libraries of DNAzyme”. *Nature Nanotechnology*.
- Errico M. (2007). “Diritto alla salute e sperimentazioni sull’uomo: la “reasonable availability” dei farmaci nei paesi in via di sviluppo”. *Sociologia del diritto*, 34(1).
- Fernandes R., V. Roy, H.C. Wu, W.E. Bentley (2010). “Engineered biological nanofactories trigger quorum sensing response in targeted bacteria”. *Nature Nanotechnology*.
- Foà S. (1998). *Il fondamento europeo del diritto alla salute. Competenze istituzionali e profili di tutela*, in Gallo C.E., B. Pezzini (eds.). *Profili attuali del diritto alla salute*. Giuffrè, Milano.
- Foster K.R., P. Vecchia, M.H. Repacholi (2000). “Risk Management: The Science and the Precautionary Principle”. *Science*, 288(5468).
- Giannini S. (2001). “La brevettabilità del vivente: i diritti coinvolti dalle biotecnologie”. *Diritto & Diritti*. [Online], URL: <<http://www.diritto.it/articoli/civile/giannini.html>>.
- Giovanetti T. (2005). *Biotecnologie e sicurezza alimentare la tutela della salute del consumatore tra Corte costituzionale e Corte di giustizia della Comunità europea*, in D’Aloia A. (ed.). *Bio-tecnologie e valori costituzionali. Atti del seminario di Parma svoltosi il 19 marzo 2004*. Giappichelli, Torino.
- Gitti A. (1998). “La Corte europea dei diritti dell’uomo e la Convenzione sulla biomedicina”. *Rivista internazionale dei diritti dell’uomo*, 11(3).
- Handl G. (2001). *Human Rights and the Protection of the Environment*, in Eide A., C. Krause, A. Rosasi (eds.). *Economic, Social and Cultural Rights. A Textbook*. Martinus Nijhoff Publishers, Dordrecht – Boston – London.
- Manfredi R. (2005). *Biotecnologie e regolazione tecnica*, in D’Aloia A. (ed.). *Bio-tecnologie e valori costituzionali. Atti del seminario di Parma svoltosi il 19 marzo 2004*. Giappichelli, Torino.
- Marino I.M. (2011). *Aspetti propedeutici del principio giuridico di precauzione*, in Guerra G., A. Muratorio, E. Pariotti, M. Piccinni, D. Ruggiu (eds.). *Forme di responsabilità, regolazione e nanotecnologie*. Il Mulino, Bologna.

- Oddedino A. (2001). “La tutela della salute è e resta ancillare rispetto alle politiche della Comunità”. *Diritto pubblico comparato ed europeo*, 1.
- Ogata S. (1990). *Introduction: United Nations approach to human rights and scientific and technological developments*, in Weeramantry C.G. (ed.). *Human rights and scientific and technological development*. United Nation University Press, Tokyo, [Online], URL: <<http://www.unu.edu/unupress/unupbooks/uu06he/uu06he03.htm>>.
- Olivieri F. (2008). “La Carta sociale europea tra enunciazioni dei diritti, meccanismi di controllo e applicazioni delle corti nazionali. La lunga marcia verso l’effettività”. *RDSS. Rivista del diritto della sicurezza sociale*, 8(3).
- Pariotti E. (2008). *I diritti umani. Tra giustizia e ordinamenti giuridici*. UTET Università, Torino.
- Pernice I. (2008). *The Treaty of Lisbon and Fundamental Rights*, in Griller S., J. Ziller (eds.). *The Lisbon Treaty: EU Constitutionalism without a Constitutional Treaty?*. Springer, Wien, New York [Online], URL: <http://www.judicialstudies.unr.edu/JS_Summer09/JSP_Week_1/Pernice%20Fundamental%20Rights.pdf>, retrieved 23 January 2010>.
- Piciocchi C. (2001). “La Convenzione di Oviedo sui diritti dell’uomo e la biomedicine: verso una bioetica europea?”. *Diritto pubblico comparato ed europeo*, 3.
- Sanderson H., S. Petersen (2002). “Power Analysis as a Reflexive Scientific Tool for Interpretation and Implementation of Precautionary Principle in European Union”. *Environment Science & Pollution Research*, 9(2).
- Shina J., S.J. Reyes, J.P. Gallivan (2010). “Reprogramming bacteria to seek and destroy an herbicide”. *Nature Chemical Biology*.
- Somsen H. (2007). *The Regulatory Challenge of Biotechnology. Human Genetics, Food and Patent Law*. Edward Elgar, Cheltenham (UK) – Northampton, Ma (USA).
- Spielmann D. (1999). *Human Rights Case Law in the Strasbourg and Luxembourg Courts: Conflicts, Inconsistencies, and Complementarities*, in Alston P. (ed.). *The EU and Human Rights*, Oxford University Press, Oxford.
- Szysczack E. (2001). *Protecting Social Rights in the European Union*, in Eide A., C. Krause, A. Rosasi (eds.). *Economic, Social and Cultural Rights. A Textbook*. Martinus Nijhoff Publishers, Dordrecht – Boston – London.
- Toebe B. (2001). *The Right to Health*, in Eide A., C. Krause, A. Rosasi (eds.). *Economic, Social and Cultural Rights. A Textbook*. Martinus Nijhoff Publishers, Dordrecht-Boston-London.
- Viola F., G. Zaccaria (2001). *Diritto e interpretazione. Lineamenti di teoria dell’interpretazione*. Laterza, Roma-Bari.
- Warbrick C. (2007). *Economic and Social Interests and the European Convention on Human Rights*, in Baderin M.A., R. Mc Corquodale (eds.). *Economic, Social and Cultural Rights in Action*. Oxford University Press, Oxford-New York.
- Xenos D. (2003). “Asserting the Right to Life (Article 2 ECHR) in the context of Industry”. *German Law Journal*, 8.

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Changing the Criminal Character: Nanotechnology and Criminal Punishment

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Abstract: While many scholars have considered the broad ethical implications of emerging technologies, far fewer have considered their potential impact on criminal sentencing. The criminal law's aim of social order, and punishment of wrongful acts, is achieved via certain "principles of punishment", which traditionally guide the structure of criminal offenses and punishment. This paper argues that use of nano-tracking devices and nano-neuroscience in the form of neuro-castration would represent a shift away from retribution as a primary justification for criminal punishment. Further, sentences utilizing nano-neuroscience may promote a new model of rehabilitation aimed at changing an offender's character, rather than his environment. Such manipulation of an offender's character, especially if it is involuntary, comprises a violation of autonomy. The paper concludes that the principles of punishment do not justify the use of nano-tracking and nano-castration, especially in light of the ethical concerns they entail.

Contents: 1. Introduction - 2. The Principles of Punishment - 3. Nano-tracking Devices - 4. Nano-neural Interventions and Implants - 5. Applications of Principles of Punishment - 5.1. Deterrence - 5.2. Incapacitation - 5.3. Retribution - 5.4. Rehabilitation - 6. Conclusion – References

But it is not true that if acts in accordance with virtue have themselves a certain character they will be done justly or temperately. The one who does them must also be in the right state of character when he acts. First, he must act knowingly, second, he must choose the acts, choosing them for their own sake, and third, he must act from a *firm and unchanging character*.

Aristotle, *Nicomachean Ethics*, 1105a (emphasis added)

1. Introduction

This paper examines how certain advances in nanotechnology might impact criminal punishment. While many scholars have considered the broad ethical implications of emerging technologies, such as neuro-nanotechnology, few have considered their potential impact on criminal sentencing. This paper discusses the potential gains and ethical implications of two types of technological advances for sentencing: advanced tracking devices enabled by nanotechnology, and nano-neuroscience, including neural implants.

The key justifications for criminal punishment – including incapacitation, deterrence, rehabilitation, and retribution – apply very differently to criminal sentences using these emerging technologies than they do to traditional imprisonment. Traditionally, the criminal law incapacitates offenders by limiting their access to most environments (e.g. via house arrest, prison, and in rare cases in the US, death), and deters offenders via external disincentives in the form of criminal punishment. Both approaches respect the offender as an autonomous rational agent: that is, they attempt to manipulate the offender's choices by altering his environment, not by altering the offender himself. However, nanotechnology, by way of implanted tracking or neural devices, may allow us to incapacitate or deter by altering an offender directly. For example, a pedophile who commits criminal sexual assault might be implanted with a nano-scale radio frequency identification (RFID) mechanism – one so small that it could never be located by the offender – that allows for continuous tracking. The offender might also be subject to “neural castration” via nano-neurological implants. Both of these sentencing measures skip a step in the usual process of attempting to change offender behavior: instead of manipulating the environment with the hopes of changing the offender's decision-making, the offender himself is (possibly permanently) changed.

I argue that such programs have a reduced deterrent effect compared to imprisonment, and incapacitate more narrowly than imprisonment – with regard to specific crimes, such as sexual or domestic assault – instead of guarding against all criminal activity. I further argue that use of these technologies may not be viewed as severe as traditional sentences, and that they are unlikely to assuage a community's moral outrage at the crime committed. Thus these new technologies may also fail to promote the principle of retribution.

Further, even though neural implants can be seen as rehabilitative, changing an offender's second order preferences (via permanent change to first order preferences) can be seen as infringement upon his autonomy. Thus the sort of involuntary manipulation

of psychological states that might occur in the case of “nano-castration” would be a severe ethical violation. Additionally, serious thought must be given to question of whether a criminal offender can effectively consent to nano-neuroscientific procedures. I will argue that such procedures are unlikely to meet Bomann-Larsen’s “appropriateness-constraint” because they cannot be tailored specifically enough to address only the criminal behavior at issue.

The paper concludes that the principles of punishment do not justify the use of at least two of the sentencing policies that might be enabled by nanotechnology; nano-tracking and neuro-castration. The principles of punishment are better met via traditional sentencing, and use nano-neuroscience can be seen as starting down a slippery-slope that will ultimately lead to violations of offender’s autonomy.

2. The Principles of Punishment

Many feel the primary aim of the criminal law is social order or control¹. This goal is achieved by certain “principles of punishment”, which guide the structure of criminal offenses and punishment. In the US, the criminal law has certain stated aims. Although US criminal law is codified into 52 criminal codes (one for each state and the District of Columbia, as well as the Federal code), there is much similarity amongst the codes, due to the influence of the American Law Institute’s Model Penal Code (MPC). The code has acted as a guide to state legislators, and instituted a wave of state reforms in criminal law after it was promulgated in 1962. Recently, the “purposes” section of the sentencing provisions of the MPC was substantially revised, representing a shift from deterrence and incapacitation to retribution as the criminal law’s primary justification².

¹ Bentham J. (1996), *An introduction to the principles of morals and legislation*. Burns J.H., H.L.A. Hart (eds.), with a new introduction by Rosen F. and an interpretive essay by Hart H.L.A., Oxford; Hart H.L.A. (1968), *Punishment and Responsibility: Essays in the Philosophy of Law*, Oxford.

² The old “purposes” section stated that:

1. The general purposes of the provisions governing the definition of offenses are:

- (a) to *forbid and prevent conduct* that unjustifiably and inexcusably inflicts or threatens substantial harm to individual or public interests;
- (b) to subject to public control persons whose conduct indicates that they are disposed to commit crimes;
- (c) to safeguard conduct that is without fault from condemnation as criminal; [...]
- (e) to differentiate on reasonable grounds between serious and minor offenses.

2. The general purposes of the provisions governing the sentencing and treatment of offenders are:

- (a) to prevent the commission of offenses;
- (b) to promote the correction and rehabilitation of offenders;
- (c) to safeguard offenders against excessive, disproportionate or arbitrary punishment; [...]

The new “purposes” section, drafted in 2004, states that:

2. The general purposes of the provisions governing the sentencing and corrections, to be discharged by the many official actors within the sentencing and corrections system, are:

- (a) in decisions affecting the sentencing and correction of individual offenders:
 - (i) to render punishment within a range of severity proportionate to the gravity of offenses, the harms done to crime victims, and the blameworthiness of offenders;
 - (ii) when possible with realistic prospect of success, to serve goals of offender rehabilitation, general deterrence, incapacitation of dangerous offenders, and restoration of crime victims and communities, provided that these goals are pursued within the boundaries of sentence severity permitted in subsection (a)(i); and

However, each of the principles of punishment listed below is cited as justification for punishment under the MPC:

1. Deterrence of harmful acts. This principle includes both specific deterrence of a particular offender from recidivating, and deterrence of the general population from committing a particular class of acts.
2. Incapacitation. This principle indicates that offenders who are not likely to be deterred may be held to prevent them from recidivating.
3. Rehabilitation. This principle envisions that an offender might be somehow taught not to recidivate.
4. Retribution. This is the principle of “just deserts”, where the offender is thought to deserve to have something bad happen to him, because he has performed a harmful act. It is also thought to perform the function of assuaging social outrage that may arise due to performance of a harmful act.³

The content and structure of the criminal law can be justified by looking to the principles of punishment. For example, the two requirements that must be met for one to be found guilty of a crime in a common law system, and the gradations of culpability, can be understood via these principles. To return a guilty verdict, a judge or jury must find the defendant (1) committed the act that caused criminal harm voluntarily (the voluntary act requirement), and (2) had a certain mental state with regard to that act (the mental state requirement). Generally, the mental state requirement means the offender must have performed the act that caused criminal harm purposely, knowingly, recklessly or negligently⁴.

Thus, an offender’s intent is crucial to determinations of responsibility and punishment⁵. Criminal harm closely related to an offender’s desires – acts that cause harm desired by the offender – are punished under the law most severely; whereas acts performed “on accident” are not punished at all. The difference in treatment between the two sorts of acts is justified by the principles of punishment in the following way: In comparison with acts performed on accident, acts closely related to an offender’s desires are (1) most likely to be *deterred* by threat of punishment; (2) more indicative of future dangerous acts, and thus the offender is a better candidate for *incapacitation* and *rehabilitation*; and (3) more morally reprehensible and thus more deserving to *retribution*. However, a person who accidentally trips and thus discharges their gun (1) would not have been *deterred* by threat of punishment; (2) is not likely to be dangerous in the future and thus is not a good candidate for *incapacitation* and *rehabilitation* (extreme klutziness notwithstanding); and (3) is not deserving of moral condemnation or *retribution*.

(iii) to render sentences no more severe than necessary to achieve the applicable purposes from subsections (a)(i) and (ii); [...]

³ Some also argue that “restoration” is a principle of punishment that should guide the criminal law system. This principle would require offenders to somehow “restore” the victim and society, or make them “whole” again. It is unclear that this principle is currently taken seriously in the US, although there have been some pilot programs aimed at introducing it. For a general discussion of restoration, see Johnstone G., D. Van Ness (2006), *Handbook of Restorative Justice*.

⁴ Model Penal Code Proposed Official Draft 1962.

⁵ Duff R.A. (1990), *Intention, Agency & Criminal Liability*, Oxford.

Further, the length or type of criminal sentences can be justified by the principles of punishment. In the US, a person who desires the death of another, and then kills them, is found guilty of first degree murder and thus is subject to more punishment than one who kills recklessly. Only a very severe penalty stands a chance of deterring the offender who directly desires to commit criminal harm. And, the “intentional” offender is most likely to be dangerous in the future, and thus is a candidate for long-term incapacitation. He is also more morally blameworthy and therefore deserves retribution.

Different theories regarding the legitimacy and purpose of the criminal law emphasize different principles of punishment as more important. Consequentialist justifications of criminal law, such as those offered by Jeremy Bentham, tend to emphasize the principles of deterrence and incapacitation, as they have easily identified consequences for social order⁶. According to the consequentialist view, in addition to identifying and punishing harmful acts already committed, the criminal law also attempts to process offenders in a way that will prevent future harm to society. The principles of deterrence, incapacitation and rehabilitation achieve this in an obvious way by either convincing or forcing an offender not to do further harm; or by changing an offender such that they are less likely to do criminal harm. Thus, the criminal law attempts to secure social order by “[...] announc[ing] to society that [criminal] actions are not to be done and [attempting] to secure that fewer of them are done”⁷.

The principle of retribution is thought to further social order by minimizing vigilante justice and strengthening citizen support for the rule of law, as well as serving some psychological aim of making victims and the community “feel better” about a crime. Retribution, however, is also thought to entail the moral condemnation of criminal acts. That is, according to the principle of retribution, it is right to punish someone even if it does nothing to further the aim of social order, because they have committed a moral wrong. As HLA Hart noted,

[...] meeting the moral evil of misconduct with suffering is, as Kant urged, good *per se*, so that, even on the last day of society, the murderer not only may but must be executed even though that execution will have no good consequences for society⁸.

Some scholars argue that retribution is the most important of the justifications for punishment⁹. According to “legal moralists” the criminal law’s primary purpose is to achieve justice by punishing those who are morally culpable in the performance of some wrongful action¹⁰. Even legal moralists, however, believe that the principles of deterrence and incapacitation serve as secondary justifications of punishment¹¹. Hart similarly argued that multiple principles of punishment grounded the criminal law. He

⁶ Bentham J. (1996).

⁷ Hart H. (1968).

⁸ Hart H. (1968).

⁹ Bradley G.V. (1999), “Retribution and the Secondary Aims of Punishment”, *The American Journal of Jurisprudence*, pp. 105-123; Moore M.S. (1988), “The Moral Worth of Retribution”, in Schoeman F. (ed.), *Responsibility, Character and the Emotions: New Essays in Moral Psychology*.

¹⁰ Moore M.S. (1988), “The Moral Worth of Retribution”, in Schoeman F. (ed.).

¹¹ Bradley G.V. (1999).

argued that while the primary aim of the criminal law was social order, the criminal law recognizes offenders as “thinkers” who should only be culpable when they can foresee the application of punishment for an act, because this is the grounds for moral culpability. The defenses available to criminal culpability, Hart argued, indicate that punishment is not applied in a common law system based purely on deterrent or incapacitative effect¹². Thus Hart attempts to “side constrain” a consequentialist theory of law with the notion that humans are agents who are responsible when they choose to commit harmful acts.

This paper will assume that all four of the justifications for punishment listed above are legitimate. This seems to be a safe assumption, given that most of the disagreement about the justifications for punishment concern which of these four principles should be considered primary. Because I conclude that none of these justifications are likely to be better served via use of the technologies discussed, my argument will remain relevant regardless of which justifying principle one considers most important.

3. Nano-tracking Devices

New technologies are already being used in an attempt to more efficiently execute existing sentencing policies. Most often, the “efficiency” sought is monetary. The US incarceration rate has almost doubled in each decade since 1970, increasing from 135 per 100,000 US residents in 1978 to 244 in 1988 to 460 in 2003¹³. As a result of this rise in prisoners, state corrections expenditures were the second fastest growing component of state budgets during the 1990s¹⁴. State prison operating expenditures totaled \$28.4 billion in fiscal year 2001, with a nationwide average annual operating cost per inmate of \$22,650¹⁵.

When compared with incarceration, home detention and electronic monitoring (EM) programs are substantially cheaper. Older EM programs, such as one in New York City, cost only \$2.91 per offender a day, or \$1,652 a year¹⁶. However, even newer, more sophisticated EM programs involving GPS tracking are considerably less expensive than incarceration. The Napa County Board of Corrections recently adopted a GPS EM program, noting that the program cost only \$15 a day in comparison to the \$109 a day cost to keep offenders in jail¹⁷.

Electronic monitoring was first used in 1984 in Florida as a part of a house arrest program¹⁸. Some sort of home confinement with electronic monitoring was in place in

¹² Hart H. (1968).

¹³ Steen S., R. Bandy (2007), “When the policy becomes the problem: Criminal justice in the new millennium”, *Punishment and Society*, 9, pp. 5-26.

¹⁴ Steen S., R. Bandy (2007).

¹⁵ Stephan J.J. (2004), “State Prison Expenditures” U.S. Department of Justice.

¹⁶ Raab S. (1991), “Electronic Monitoring Is Planned for Detainees”, *The New York Times* (New York Region).

¹⁷ West E. (2008), “Napa County Department of Corrections Home Detention and Work Furlough Programs”, *Napa County Board of Supervisors*, 4.

¹⁸ Mainprize S. (1992), “Electronic Monitoring in corrections: Assessing cost effectiveness and the potential for widening the net of social control”, *Canadian Journal of Criminology*, 1.

all 50 US states by 1990¹⁹. In most cases, electronic monitoring is done via an ankle bracelet. At timed intervals, the ankle bracelet sends a radio frequency or GPA signal to a receiver. If an offender moves outside of an allowed range, the police will be notified. The first generation bracelets consisted in a radio-frequency transmitter unit that sent a signal to a fixed location receiving unit in the offender's residence. The residence unit then used either a land line or a cellular network to relay information to a service center computer. If the offender is not at the residence at times stipulated, an alert message is sent to the service center, and then relayed to the supervising probation or parole officer²⁰.

As mentioned above, second-generation electronic monitors include GPS technology. The offender either carries a GPS cell phone unit that receives a signal from the ankle unit, or both functions are combined into one ankle unit²¹. At least fourteen states have statutory provisions regarding GPS tracking of sex offenders²². A Florida statute, entitled Jessica's Act, requires persons convicted of sexual offenses against children under the age of twelve to be subject to lifetime electronic monitoring. Pennsylvania and California have similar provisions²³. A Massachusetts statute allows courts to impose GPS tracking systems on domestic abusers who have violated restraining orders and have been identified as dangerous after an assessment²⁴. In some of the programs, the offenders bear the cost of monitoring: in Massachusetts, they are charged \$8 a day for a cell phone-like device that clips to a belt, an ankle bracelet and a home charger. The offenders' movements are then monitored by three control centers, and if they break an "exclusion zone" around the victim or her children, the police are notified²⁵. Twelve other states have passed similar legislation, and as a result, about 5,000 domestic abuse offenders are being tracked nationwide²⁶.

However, GPS technology has its limitations. In the UK, more than 17,000 individuals, including criminals and suspects released on bail, are currently subject to monitoring under curfews requiring them to stay at home up to 12 hours a day. However, almost 2,000 offenders a year escape monitoring by tampering with ankle tags or tearing them off. The UK Ministry of Justice is thus investigating the use of subdermal chips²⁷. In addition, officials reported losing track of offenders when they were in the shadow of large buildings.

Many feel that radio frequency identification ("RFID") technology is the next generation of tracking device²⁸. In 2004, the Food and Drug Administration approved use

¹⁹ Padgett K.G., W.D. Bales, T.G. Blomberg (2006), *Under Surveillance: An Empirical Test of the Effectiveness and Consequences of Electronic Monitoring*.

²⁰ Padgett K.G., W.D. Bales, T.G. Blomberg (2006).

²¹ Padgett K.G., W.D. Bales, T.G. Blomberg (2006).

²² Hinson Z. (2008), "Conversation: GPS Monitoring of Domestic Violence Offenders: GPS Monitoring and Constitutional Rights", *Harvard Civil Rights - Civil Liberties Law Review*.

²³ Hinson Z. (2008).

²⁴ Hinson Z. (2008).

²⁵ Green A. (2009), *More States Use GPS to Track Abusers The New York Times*, (Newburyport 2009).

²⁶ <http://www.nytimes.com/2009/05/09/us/09gps.html?_r=3&th&emc=th>.

²⁷ Brady, B. (2008), "Prisoners 'to be chipped like dogs'", *The Independent*, United Kingdom.

²⁸ Rosenberg I.B. (2007), "Involuntary Endogenous RFID Compliance Monitoring as a Condition of Federal Supervised Release - Chips Ahoy?", *Yale Journal of Law & Technology*.

of subdermal RFID in humans. Currently, over 2000 people have RFID chips implanted in their bodies, including children in Britain and the Mexican Attorney General and his staff²⁹. The Department of Defense is supposedly considering use of RFID technology to track soldiers and carry information about their health onto the battlefield³⁰. To date, in the US there has been no federal legislation either encouraging or prohibiting the use of tracking implants in the criminal justice system³¹.

Unlike GPS technology, which relies on a network of satellites to transmit signals of a wearer's location, RFID tags communicate with proximate readers via radio frequency³². This, however, requires that a RFID infrastructure be in place³³. Some infrastructure already exists in the US: in many states, for example, RFID systems allow for cars to avoid manually paying tolls, instead using a RFID "E-Z pass"^{34 35}. It seems state criminal justice systems could utilize these already existing networks, and implement new ones, as a means to start using RFID chips as a way to track criminal offenders. It is possible that at some point federal legislation may allow for a unified tracking system across state borders.

RFID chips, like ankle bracelets, may still be removed by offenders if their implantation site is known. Nanotechnology, however, will inevitably enable smaller, and more efficient, RFID tagging. A 2007 article in the magazine "Industry Week" makes this clear³⁶.

Let's start with how RFID works. Imagine something that looks a little like a 2"x2" decal with an X-shape on it and a tiny dot at the center. The dot is a microchip. The X is the antenna, which, in our example, uses silver as a conductor. With current technology, the effective reach of the device is governed by the size of the antenna. That means more silver is required, increasing size and cost. That's where nanotechnology can help. Nanotechnology could enable a denser layer of silver nanoparticles on a thin film, which would make possible a smaller and thinner antenna that could provide the same (or better) signal. Smaller size, greater functionality, less cost. Now let's throw in durability. Decreasing the size of the antenna can also improve the longevity of the devices. Larger, thicker antennae are more susceptible to being bent and broken. In addition, there's an air-tight package around the antenna, which can crack, exposing the antenna silver to oxidizing air. Smaller units offer less room for damage.³⁷

A bit later in the article, the author notes:

²⁹ Rosenberg I.B. (2007).

³⁰ Rosenberg I.B. (2007).

³¹ Rosenberg I.B. (2007).

³² Rosenberg I.B. (2007).

³³ Rosenberg I.B. (2007).

³⁴ Wolfe J. (2005), "Nano Noses Into RFID", *Forbes*.

³⁵ <http://www.forbes.com/2005/11/23/rfid-nano-wolfe-in_jw_1123soapbox_inl.html>.

³⁶ Rickert S.E. (2007), "Taking The NanoPulse – My RFID Tag Is Smaller Than Your RFID Tag", *Industry Week*.

³⁷ <http://www.industryweek.com/articles/taking_the_nanopulse_my_rfid_tag_is_smaller_than_your_rfid_tag_13702.aspx>

When RFID prices get to a penny, where can the market go? Just about anywhere. Tags can go into Fido's collar to help the dog catcher bring him home safe. Soldiers and equipment in the field would never be 'off the grid'³⁸.

And criminal offenders could be continuously tracked for the rest of their lives.

If a nano-RFID doesn't already exist, it soon will. And, as noted above, it seems that the criminal justice system would certainly be interested in cheaper, more reliable tracking of offenders, especially given that tracking has already been accepted as a legitimate sentencing tool³⁹.

4. Nano-neural Interventions and Implants

Nanotechnology has already been used to detect activity of individual neurons via platinum nanowires⁴⁰. This allows for an understanding of the brain at the neuron-to-neuron interaction level. And because nanowires can deliver electrical impulses as well as receive them, they allow for the direct stimulation of neurons which can then allow for manipulation of brain processes⁴¹: and, potentially, manipulation of thought.

In addition, quantum dot technology is being used to gather information in the brain at the level of the neuron. Nano-sized functional quantum dots can help build data-capture devices that are easy to use by neuroscientists⁴². Many feel that nanotechnology will eventually allow for targeted interactions with neurons and glial cells, the cells responsible for signal transmission in the brain. As explained by Armin Grunwald:

Nanotechnology offers a range of possibilities for gathering, storing, and distributing personal data in an increasing extent... [Furthermore] passive observation of people could, in the distant future, be complemented by actively manipulating them – for instance, if it would be possible to gain direct technical access to their nervous system or brain. These possibilities are regarded by some to be not only realistic, but even certain...⁴³

It seems clear that nanotechnology will eventually allow us to visualize and track functional responses in neurons, and this means we will be provided information about a

³⁸ Rickert S.E. (2007).

³⁹ However, there is some worry that the statutes allowing advanced tracking of offenders will fail to pass constitutional review. Although the Supreme Court has not yet issued a ruling dealing with GPS tracking devices, statutes that continuously track offenders – including in protected areas such as the home – might violate the wearer's Fourth Amendment rights against unreasonable search and seizure. However, a statute that only transmitted data of the offender's whereabouts when he had entered a "forbidden zone" would avoid this problem. Similarly, any statute that tracks all offenders of a certain type – such as sex offenders – without an individualized finding of dangerousness might violate the Fourteenth Amendment.

⁴⁰ Jain K. (2006), "Role of Nanotechnology in Developing New Therapies for Diseases of the Nervous System", *Nanomedicine*, 1, pp. 9-12.

⁴¹ Jain K. (2006).

⁴² Silva G.A. (2006), "Neuroscience Nanotechnology: Progress, Opportunities and Challenges", *Nature Neuroscience*, 7, pp. 65-74.

⁴³ Grunwald A. (2005), "Nanotechnology - A New Field of Ethical Inquiry?", *Science and Engineering Ethics*, 11, pp. 187-201.

person's thoughts remotely. In addition, several brain probes and implants are already being used in neurosurgery, although many of them are still investigational⁴⁴. Nanotubes, particularly made of carbon, hold great promise for replacing conventional silicone implants in the brain, "[...] because of their interesting electronic properties and reduction in scar formation"⁴⁵.

Ultimately, such nano-neurological implants could be used not only to track neuronal activity, but to manipulate neuronal activity. This translates into the ability to *manipulate* thought; possibly via transmission or implantation of desires or beliefs⁴⁶.

As indicated above, it is most likely that nanotechnology, including neuro-nanotechnology, will initially be used to more effectively achieve sentencing policies already in operation. For example, imagine a defendant, John, was found guilty of the molestation and murder of a young boy who lived next door. As a part of his sentence, John is forced to register as a sex offender. He is also required to participate in a castration program. Below we will consider how nano-neuroscience might be used on an offender such as John.

Eight US states (California, Florida, Iowa, Texas, Oregon, Wisconsin, Louisiana, and Montana) have chemical castration laws⁴⁷. California was the first state to use chemical castration as a punishment for sex offenders⁴⁸. In cases where the victim is under 13 years of age, California judges can require first-time offenders to undergo chemical castration. After a second offense, treatment is mandatory. In Iowa and Florida, offenders may be sentenced to chemical castration in all cases involving serious sex offenses. As in California, treatment is mandatory after a second offense. Louisiana Governor Bobby Jindal has signed a bill allowing Louisiana judges to potentially sentence all convicted rapists to chemical castration⁴⁹.

Depro-Provera is the drug most often used for chemical castration⁵⁰. It is an analogue of the female hormone progesterone, used to reduce the normal level of testosterone in a male by fifty percent – a level equal to the level found in pre-pubescent boys⁵¹. The drug reduces sex-drive, often diminishing ejaculator fluid to zero. Capacity for an erection can disappear almost immediately or slowly over some months. In some, however, the capacity for an erection may never disappear completely⁵².

⁴⁴ Jain K. (2006).

⁴⁵ Jain K. (2006).

⁴⁶ Sifferd K.L. (2008), "Nanotechnology and the Attribution of Responsibility", *Nanotechnology Law and Business*, 5, pp. 177-189.

⁴⁷ Greeley H.T. (2008), "Neuroscience and Criminal Justice: Not Responsibility but Treatment", *Kansas Law Review*, 56, pp. 1103-1138; There is another problem with castration as a sentencing tool: it may be discriminatory, as it only applies to male offenders.

⁴⁸ Smith K.L. (1998), "Making Pedophiles Take Their Medicine: California's Chemical Castration Law", *The Buffalo Public Interest Law Journal*, pp. 1-42.

⁴⁹ Millholon M. (2008), "Jindal Signs Chemical Castration Bill", *Louisiana Advocate*, p. 6.

⁵⁰ Smith K.L. (1998).

⁵¹ Smith K.L. (1998); *Skinner v. State of Oklahoma, Ex. Rel. Williamson*, 316 U.S. 535 (1942), held that forced punitive sterilization is unconstitutional. It seems unlikely that the current Supreme Court will uphold the Louisiana chemical castration statute, which provides a form of punitive forced sterilization.

⁵² Smith K.L. (1998).

Depo-Provera has potentially serious side effects, including thromboembolism, weight gain, fatigue, malaise, mild depression, hypertension, hyperglycaemia, and liver problems⁵³. Moreover, to maintain the effects of Depo-Provera, a high volume of injection is required regularly. Most chemically castrated men will probably receive 400 to 500 milligrams of Depo-Provera per week, which amounts to an injection of 2.5 milliliters into each buttock each time⁵⁴. This high volume of injections, and the subsequent side effects, may contribute to the high dropout rate seen with voluntary chemical castration⁵⁵.

In addition, there is no guarantee that chemical castration actually works. Individuals vary in their response, and men given oral doses as high as 700 milligrams per day have still reported regular sexual arousal⁵⁶. Studies indicate that the drug, when used in conjunction with ongoing counseling, allows most pedophiles to self-regulate their sexual behavior. However, because the drug does not eradicate sexual attraction to children, and often does not completely eliminate sexual activity; its success often depends upon an offender's attitude to the therapy. If an offender wants to stop preying upon children, the drug can help them to do so. If they do not, the drug can only hinder their attempts to perform sexual assault.

Let's go back to our sexual offender, John. We first might imagine that nanotechnology could be used in addition to chemical castration. John could agree to have nanotechnology (such as functionalized quantum dots) implanted in his brain to gather information. Multiple quantum dots could be implanted, some in the area where the man held representations of children, others in areas indicating sexual arousal, and another few on the pathway between these two areas. If the dots ever detected simultaneous activity, this information was transmitted to John's parole officer who was then under an obligation to track John down and investigate. This would provide a safe-guard to ensure the chemical castration was working.

Or, neurological castration could be achieved via direct inhibition of activity in certain parts of the brain (e.g., within the hypothalamus), or by blocking connectivity between areas of brain (e.g. between representations of children and sexual arousal). Remember, some neuroscientists claim that active manipulation of brain states via nanotechnology is not just realistic, "... but certain⁵⁷". We are already inhibiting brain states in cases of epilepsy and Parkinson's. It may be that a nano-technological approach to castration may be more successful, and have far fewer side effects, than current methods⁵⁸.

⁵³ Harrison K. (2007), "The High-Risk Sex Offender Strategy in England and Wales: Is Chemical Castration an Option?", *The Howard Journal of Criminal Justice*, 46, pp. 16-26.

⁵⁴ Macready N. (1996), "Chemical Castration for Paedophiles Approved", *BMJ*, 312, 1.

⁵⁵ Macready N. (1996).

⁵⁶ Macready N. (1996).

⁵⁷ Grunwald A. (2005).

⁵⁸ Again, however, there are questions about whether neuro-castration would pass constitutional muster. The Eighth Amendment forbids punishments that are "cruel and unusual". Such a punishment does not appear to be crueler than current measures designed to create the same deterrent effect, such as permanently incapacitating, imprisoning or institutionalizing, or chemically castrating an individual. Nano-neuroscientific approaches could be deemed "unusual" in the common language sense of the word, but probably not in the way the Supreme Court has interpreted the Eighth. To be "unusual" in this sense a punishment must be rare

One might imagine that neurological castration could just be the beginning of nano-enabled neurological sentencing. If it became possible to neurologically inhibit strong violent responses to stimuli, the state might offer offenders the chance to submit to this operation in exchange for a shortened or commuted sentence⁵⁹. Granted, at the moment this possibility is more fiction than science. However, given the success in drug interventions on aggressive behavior – for example, with tranquilizers and some anti-depressants – it doesn't seem impossible that neuroscience could discover a more targeted means of delivering the same result.

5. Application of Principles of Punishment

5.1. Deterrence

The principle of deterrence is supposed to reduce crime by setting the expected cost of committing a crime high enough to dissuade potential criminals from choosing to commit illegal acts⁶⁰. The idea behind deterrence is that potential criminals have a choice regarding their actions, and they will opt to commit a crime if the expected gain exceeds the expected cost⁶¹. The expected cost is the probability of being punished, reflected in arrest and conviction rates, operating in conjunction with severity of punishment⁶².

Measuring deterrent effect is notoriously difficult⁶³. It is generally thought that more severe punishments have a greater deterrent effect⁶⁴. However,

[a]t least since the time of Beccaria, it has been commonly accepted that the certainty of detection and punishment is of greater consequence in deterring people from committing crimes than is the severity of the penalty⁶⁵.

Criminals, like all human beings, are not purely rational actors, and they have a tendency to discount future punishment in light of immediate gains.

One expects that any sort of monitoring system where the offender is free to move about his home or within his community will have a lesser deterrent effect than incarceration, if the probability of arrest and conviction is high enough. Incarceration will be

(in that it is not practiced by a critical mass of states) and violate “evolving standards of decency”. See *Furman v. Georgia* 408 US 238 (1972).

⁵⁹ Greeley has suggested that deep brain stimulation (DBS) could also provide a method of inhibiting activity in areas where over-activity may contribute to criminal activity.

⁶⁰ Becker G.S. (1968), “Crime and Punishment: An economic approach”, *Journal of Political Economy*, 78, pp.169-217; Mendes S.M. (2004), “Certainty, Severity, and Their Relative Deterrent Effects: Questioning the Implications of the Role of Risk in Criminal Deterrence Policy”, *The Policy Studies Journal*, 32, pp. 59-74.

⁶¹ Mendes S.M., M.M. McDonald (2001), “Putting the Severity of Punishment Back in the Deterrence Package”, *Policy Studies Journal*, 29, pp. 588-610.

⁶² Mendes S.M., M.M. McDonald (2001).

⁶³ Nagin D.S. (1998), “Criminal Deterrence Research at the Outset of the Twenty-First Century”, *Crime and Justice*, 23, pp. 1-42.

⁶⁴ Andenaes J. (1966), “The General Preventive Effects of Punishment”, *University of Pennsylvania Law Review*, 114, pp. 949-983.

⁶⁵ Andenaes J. (1966).

viewed by most potential offenders as a more severe punishment because it is a greater infringement upon liberty. This is why incarceration is reserved for more severe felony offenders. One who is being electronically monitored while under house arrest may enjoy the comforts of their own home, eat the food they wish, and visit with friends and family. An offender being monitored who is not on house arrest enjoys relative freedom to move about their community and go to a job, school, church, etc. For the potential offender considering the cost of committing a crime, incarceration is going to be granted a heavier weight than monitoring, and thus would seem to have a larger deterrent effect.

For example, Jasper is a young man considering stealing a car so he can drive to Florida to see his girlfriend. Before he commits the crime, however, he is likely to consider the possibility that he might get caught, tried, and criminally punished. If Jasper knows he will be released under electronic monitoring if he is found guilty of stealing the car, he is probably more likely to commit the crime than if he thinks he will serve 5-7 years in prison for stealing the car.

Electronic monitoring, however, does appear to have *some* deterrent effect, even if it is much less of a deterrent than incarceration⁶⁶. One study suggested the longer the amount of time on electronic monitoring, the lower the likelihood of recidivism. This effect, however, varied by offender type⁶⁷. One might imagine that new generation nano-tracking may have a slightly higher deterrent effect than ankle bracelet monitoring, due to its potential permanence within the offender's body and the inability of offenders to tamper with the tracking device. As indicated above, nano-tracking also has the possibility of being life-long; in the very least, the tracking device will be a permanent fixture in an offender's body, even though it may be turned off.

This slight increase in deterrent effect in comparison to traditional monitoring systems, however, would seem to be outweighed by the ethical concerns raised by the technology. Although an implanted nano-tracking device does not attempt to manipulate offender decision-making, it does breach the traditional "self" designator: the skin-boundary. More worrying, though, is the permanence of nano-tracking devices, especially when considered in conjunction with the geographic range over which offenders can be tracked. Nano-tracking, like all new generation monitoring, might allow for global tracking of offenders, instead of just monitoring whether an offender leaves or infringes upon a specific geographic area.

These potential gains – from the perspective of law enforcement – mean that offenders would have to either consent to be monitored wherever they might go for the rest of their lives, or trust the government to "turn off" the tracking device when their sentence had been served. In many cases the former may violate the idea that a sentence should be proportional to the particular crime for which is found guilty. This worry about the proportionality will be discussed in more detail below under the principle of retribution. And trusting the government to switch off the tracking device seems unwise. Currently, the United States National Security Agency has attempted to justify

⁶⁶ Gainey R.R., B.K. Payne, M. O'Toole (2000), "Relationships Between Time in Jail, Time on Electronic Monitoring, and Recidivism: An Event History Analysis of a Jail-Based Program", *Justice Quarterly*, 17, pp. 733-752.

⁶⁷ Gainey R.R., B.K. Payne, M. O'Toole (2000).

warrantless monitoring of international and domestic phone calls as a part of the “war on terror”⁶⁸. Permanent tracking devices capable of global monitoring seem ripe for abuse.

Let’s now consider whether the use of nano-castration can be justified by the principle of deterrence. There are no reliable studies measuring the deterrent effect of the threat of castration versus the threat of incarceration. One would hope that castration would be a sentencing option only for fairly serious sexual crimes. Therefore, one would think the offender’s crime would also warrant a fairly long sentence of incarceration. Given these two options, incarceration would be likely to have at least the same deterrent effect, and possibly a stronger deterrent effect, when compared to castration. Although there is no doubt that limiting a person’s sexual activity has severe ramifications for quality of life, it still seems that incarceration would have a stronger deterrent effect, because incarceration is a more encompassing limitation of liberty. When one is chemically castrated, one’s sexual life is restricted (but not permanently); but if one is incarcerated, *all* aspects of a person’s life are restricted. In the case of nano-castration, the castration would be permanent, and thus a potentially stronger deterrent effect than chemical castration.

However, both chemical and nano-castration, if administered as involuntary programs, or if administered in cases where an offender feels they have no reasonable means to refuse, are ethically troubling because of the way in which they may violate offender autonomy in two different senses. First, they may impact second order desires via manipulation of first order desires. And second, the offer of castration in exchange for a lighter sentence may be coercive and thus an infringement of autonomy.

Bomann-Larsen argues that autonomy is the capacity to act according to one’s own decisions, without the controlling influence of others, and to form these decisions on the basis of one’s own beliefs, desire and values⁶⁹. She further claims that interventions, such as castration, which impair the motivational capacity of an agent decrease her autonomy. Similarly, Gerald Dworkin has argued that autonomy is the capacity to raise the question of whether one identifies with or rejects the reasons for which one acts³⁶. Dworkin argues that autonomy is a

[...] second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes, and so forth and the capacity to accept or attempt to change these in light of higher-order preferences and values. By exercising such a capacity, persons define their nature, give meaning and coherence to their lives, and take responsibility for the kind of person they are [34: 20].

While the threat of incarceration may attempt to deter a person from acting upon certain first-order desires (such as the desire to murder or perform a sexual assault), it does not hinder his or her ability to reflect upon and hold second-order values. Neither does incarceration itself. One may hold dearly to a selfish preference to hold one’s own interests above others, or to cause others harm, while in prison. However, a person who is

⁶⁸ <<http://www.nytimes.com/2005/12/21/politics/21nsa.html?ex=1292821200&en=91d434311b0a7ddc&ei=5088&partner=rssnyt&emc=rss>>

⁶⁹ Bomann-Larsen L., “Voluntary Rehabilitation? On Neurotechnological Behavioural Treatment, Valid Consent and (In)appropriate Offers”, *Neuroethics*, pp. 1-13.

“[...] kept ignorant or who is lobotomized or who is manipulated in various ways” suffers from infringement upon his autonomy [34:17]. Involuntary castration doesn’t just stop a person from acting upon first-order desires; it changes their first-order desires. It may also render second-order preferences unnecessary, or ineffective. Hence, it is a violation of offender autonomy.

Imagine the case of two different convicted pedophiles, Robert and Frank. Robert hates the fact that he has first order desires to have sex with young boys. He wishes these first order desires weren’t effective, and instead wants to have first order desires for normal sexual relations with an adult. Frank, on the other hand, thinks he is showing real love for the boys he abuses. He values being the sort of person who has sexual relations with boys, and is glad his first order desires for sex with boys are effective.

Incarcerating Robert and Frank need not have any impact on their first order sexual desires, or on their second order values regarding their sexual preferences. They are still likely to have sexual desires, although they cannot be acted upon. And although incarcerated, Robert and Frank may still feel badly, or good, about these first order desires. However, if we castrate Robert and Frank, especially via means that would affect permanent change, we take away a whole category of first order desires. We also make ineffective – in a sense, we might as well erase – their second order sexual preferences as well. That is, their higher order desires to make certain first order desires effective regarding their sexual lives become useless, because first order desires for sex no longer arise. Thus, autonomy is impacted because second order desires are impacted.

And in the case of nano-castration, this impact on autonomy is just a bit more worrying, because it can’t be undone: the castration is permanent. Therefore Robert and Frank’s characters are permanently altered.

But what about voluntary nano-castration? Might we offer castration in exchange for a lighter or shorter sentence? One should be allowed, according to Bomann-Larsen, “to tie ones own hands” regarding specific motivations while still preserving their autonomy [33]. But even so, consent for more specific motivational interventions is invalid if the offer is inappropriate because it is coercive. To not be coercive, an offer must meet the “appropriateness-constraint” [33]. This constraint means that the treatment should not go beyond what is necessary in order to correct the behavior for which the criminal is imprisoned. In the case of castration, it would seem that this constraint cannot be met: castration necessarily impacts all sexual behavior, not just deviant or criminal sexual behavior. And again, with nano-castration, sexual behavior would be effectively eliminated permanently.

In sum, a traditional sentence of incarceration at the very least equally serves the principle of deterrence when compared to castration. Further, nano-castration isn’t likely to be any more of a deterrent than chemical castration. But any sort of castration entails serious ethical concerns because it changes first order preferences and makes second order preferences ineffective. Thus, castration violates an agent’s autonomy. And nano-castration is even more worrying than chemical castration because the effects of such an operation would be permanent.

5.2. Incapacitation

The Federal Sentencing Guidelines state that a repeat offender is “more culpable”. This increased culpability is not intended as a judgment of the instant criminal act or of the level of wrong-doing exhibited. Instead, the Sentencing Guidelines acknowledge that one goal of sentencing is to recognize and incapacitate those who are likely to be dangerous in the future; it is a “[...] judgment about the defendant’s will in general, his character. [...] The habitual offender has shown himself to be impervious to deterrence⁶⁷”.

Traditionally, the criminal law responds to the increased culpability of the recidivist by incarcerating him: the dangerous offender’s ability to commit crimes is controlled by restricting his access to people and things. It is thought that the long sentences imposed on the repeat offender exhibit an intention to “[...] warehouse career criminals until their energy for criminal acts has waned⁷⁰”.

The traditional means of incapacitation – placing an offender in a prison cell – incapacitates with regard to *any* further crime. An offender who is sent to prison for 45 years after his third rape conviction isn’t just kept from committing future rapes; he is incapacitated with regard to all possible crimes. However, monitoring offenders, including monitoring via nano-tracking devices, isn’t incapacitative in this sense. Even an offender on monitored house arrest still has some chance of recidivating because many crimes can be committed from the home. Further, if the offender were to leave the home in violation of his house arrest, it is likely that he would be able to commit crimes before he was captured. Similarly, an offender who was monitored and asked to stay away from certain persons or places could easily commit crimes violating these rules before they were caught.

Even though house arrest may incapacitate to some degree, the primary aim of a tracking device, nano or otherwise, is not to incapacitate, but to deter the offender, and to find an offender if they violate their parole or commit a new offense. So it would seem that the use of nano-tracking cannot be justified by the principle of incapacitation.

Nano-neural implants, such as one which neurologically castrates an offender, may incapacitate with regard to specific types of crime (e.g. sexual assaults). However, it is unlikely an implant could incapacitate with regard to all crime as a prison cell does (and if it could, it would certainly violate Bomann-Larsen’s “appropriateness-constraint” by eliminating all anti-social behavior in response to conviction for a particular crime).

Targeted incapacitation may have some value, as it could address the threat of recidivism in a more offender-specific manner without denying an offender all their fundamental liberties. For example, it seems pretty clear that castration may incapacitate with regard to sexual, but not other, crimes. In this case the tax payers may be seen as getting more “bang for their buck”: the offender is incapacitated without society having to bear the cost of housing and feeding the offender. And the offender gets to enjoy some liberties while they are incapacitated with regard to their specific criminal tendency.

However, as discussed above, there is an important ethical difference between incapacitation via incarceration and incapacitation via neurological interventions. Inca-

⁷⁰ Bradley G.V. (1999), “Retribution and the Secondary Aims of Punishment”, *The American Journal of Jurisprudence*, pp. 105-123.

pacitation via incarceration or house arrest limits offenders' choices for behavior without necessarily changing their first order desires or breaching their autonomy – at least in the sense that they are able to continue to review their desire based upon second-order preferences. Incapacitation by manipulation of internal chemical states, as accomplished by chemical castration, or by direct manipulation of desires, as nano-castration might enable, changes the behavior of an offender by changing preferences, not by changing an offender's ability to act upon them⁷¹.

In theory, nano-neurological interventions may someday enable direct manipulation of second-order preferences via manipulation of the brain – although admittedly current science is not even close to knowing where in the brain such second order preferences exist. If such a surgery were to become possible – where second order preferences could be inhibited or created within a person's brain – this sort of surgery would be even more of an ethical violation than castration, because it would constitute direct manipulation of a person's values or character.

5.3. Retribution

The justifications for criminal punishment tend to wax and wane in their influence upon criminal justice policy based upon political zeitgeist. Indeed, in an attempt to explain the dramatic increase in incarceration rates in the past few decades, some have argued that there has been an ideological shift in the principles of punishment: while rehabilitation was considered an important aim of punishment up to the early 1970s, rehabilitative programming is now a tiny percentage of penal costs⁷². In the 1980s, sentencing that was seen as “tough on crime” gained political capital and increased substantially. As Michael Tonry notes,

Some other governing rationale for sentencing policy was bound to take the place left empty when rehabilitation lost favor. In both academic and policy circles, that place was taken (sometimes implicitly) by retribution or ‘just deserts’⁷³.

Retribution morally condemns a criminal act and offender, and metes out punishment (an offender's “just deserts”) based upon the level of moral wrongdoing he has committed. In so doing, retribution “permits consideration of popular revulsion toward certain kinds of offenses⁷⁴”. That is, the level or type of sentence may be chosen in part to acknowledge, or in response to, the moral outrage of the community.

⁷¹ As is discussed below, some criminal justice rehabilitative programs attempt to do this as well, such as drug addiction interventions and job training. However, both of these rehabilitative programs work by the normal means of learning. If an offender really wanted to resist the effects of such programming, they could hold onto their second order preferences and go back to using drugs or stealing after the programming were over.

⁷² Steen S., R. Bandy (2007). “When the policy becomes the problem: Criminal justice in the new millennium”, *Punishment and Society*, 9, pp. 5-26.

⁷³ Tonry M. (1996), “Sentencing Matters”, *Journal of Criminal Justice*, 24(6).

⁷⁴ Bradley G.V. (1999).

In short, it is unclear that either of the nano-technologies discussed above provide an offender with his “just deserts” when contrasted with incarceration. This is because, for reasons discussed above, both nano-tracking and nano-castration are in some ways *less* severe punishments than traditional incarceration because they allow for more offender freedom. However, the permanency of these interventions also makes them seem *more* severe than is warranted.

The principle of retribution requires that a criminal sentence be proportional to both the crime committed and the type of offender. Thus, the crime of homicide warrants a more severe sentence than the crime of theft, and a 12 year old offender, or an insane offender, are less culpable than a normal adult offender. It would seem that the principle of retribution might justify house arrest or monitoring as a sentence for minor crimes. However, in these cases nano-tracking would seem to be “overkill” because it can be both global and permanent. Offenders found guilty of such minor crimes would have to either consent to be monitored for the rest of their lives, or trust the government to “turn off” the tracking device when their sentence had been served. It is difficult to imagine the sort of crime would be serious enough such that it be proportional to impose a possible lifetime of monitoring, but not serious enough to warrant incarceration. Tracking devices that can be removed would have the guarantee of being turned off, and thus proportional.

With regard to nano-neuroscientific interventions, it would seem these are only appropriate “just deserts” for serious crimes, ones that traditionally warranted at least some incarceration. No crime creates more “moral outrage” than sexual offenses against children. One can only imagine the outcry if a pedophiliac offender was released after nano-neural interventions. If the public sees incarceration as a fair and just response to this sort of offense, it seems possible that castration will fail to satisfy to the moral outrage of the community. Overall, a community may not feel satisfied with sentences that provide an offender with more personal liberty, or have a rehabilitative “feel” (as castration might), and so in this sense, this sentence may be too lenient to be retributive.

On the other hand, the reason why nano-castration fails Bomann-Larsen’s “appropriateness constraint” is because it isn’t appropriately proportional to the specific crime committed: it is too broad. So in this sense castration would seem to be too severe a sentence, or too retributive.

In sum, it seems the principle of retribution cannot justify the use of the new nano-enabled technologies⁷⁵. That is, it doesn’t seem that the principle of retribution is more efficiently or better met via sentences using the nanotechnologies. And once again, the ethical concerns implicated by the technologies must be kept in mind.

⁷⁵ As an aside, it is interesting to note that the current emphasis on retributive sentencing has resulted in a shift at both the state and federal levels away from indeterminate sentencing systems – where the judge or jury are asked to determine the appropriate sentence – to determinate ones, whereby conviction of a specific crime results in a specific sentence. Steen S., R. Bandy (2007). Thus many of the sentencing strategies enabled by emerging technologies, including electronic monitoring and chemical castration, may automatically follow from a specific type of guilty verdict. This contributes to worries about involuntary rehabilitation programs, discussed below.

5.4. Rehabilitation

Rehabilitation is the idea that offenders can be reformed such that they won't recidivate. For the first seven decades of the 20th century, rehabilitation was often thought to be the dominant principle of punishment, especially among correctional elites and criminologists⁷⁶. Rehabilitation has since fallen out of favor as a justification for punishment, except in the realm of juvenile justice – and more and more juveniles are now being sent to adult court so they are eligible for “adult” sentences⁷⁷. The Federal sentencing guidelines outright reject rehabilitation as a goal of punishment⁷⁸.

Nano-tracking would seem of little relevance to rehabilitation as it isn't thought to have any rehabilitative effect. However, nano-neuroscience could potentially allow us to re-embrace the principle of rehabilitation by providing a means to directly change offenders into law-abiding citizens. As mentioned above, one might imagine that nano-castration could just be the beginning of criminal rehabilitative programming using neuroscience to remove anti-social behavior. One wonders whether nano-neuroscience, or other neuroscientific techniques such as DBS, could eventually be a source of what some might call an “artificial conscience”, via methods similar to the government imposed chip that stopped Spike the vampire from feeding in the fabled television show, *Buffy the Vampire Slayer*⁷⁹.

The criminal law assigns responsibility based upon the fundamental assumption that an offender “owns” his intentions, or beliefs and desires, and if those intentions cause criminal harm, he can be punished⁸⁰. Virtue ethicists, such as Aristotle – cited at the beginning of this paper – add the requirement that virtuous or evil acts come from a “firm and unchanging” character trait; a trait that “goes all the way down”. Aristotle feels that such acts are indicative of the sort of person who performs them; therefore, a choice to commit homicide that springs from one's character truly deserves to be labeled an immoral act and punished⁸¹. Note that this requirement agrees with the commonsense way we speak of ourselves: when we do things outside our character, we often say “something came over me” or “I wasn't myself”. Further, Aristotle's requirement is reflected in aspects of our criminal justice system; “three strikes laws”, and aggravating factors at capital sentencing that look to future dangerousness, for example. When one acts out of character it is less likely a judge or jury will find any criminal harm was committed “purposely” (the level of intent which earns the highest level of criminal culpability). However, when one is acting against or outside of character – for

⁷⁶ Cullen F.T., P. Gendreau (2000), *Assessing Correctional Rehabilitation: Policy, Practice, and Prospects*, In *D. o. Justice* (ed.), 3, Washington, DC.

⁷⁷ Bradley G.V. (1999).

⁷⁸ 28 U.S.C. § 994(k).

⁷⁹ Every time Spike attempted a violent act against humans, the “chip” caused him severe head pain preventing him from performing the act. Eventually he stopped trying to act immorally. The question posed to the characters on the show (and the viewers) were: (1) To what extent is the altered Spike different than those of us who act morally due to the inculcation of moral rules? (2) Is Spike now a “good” or “bad” guy? (3) The difference between humans and vampires was that they lacked a soul: Can we now say that Spike has a soul?

⁸⁰ Duff R.A. (1990).

⁸¹ Aristotle (1985), *The Nicomachean Ethics*, Indianapolis.

example, when a criminal defendant has no prior criminal record – he is likely to be given a lesser punishment.

As indicated above, involuntary manipulation of psychological states via nano-technology, even in the name of rehabilitation, would appear to be a severe violation of autonomy because it would permanently render useless an offender's ability to second-order preferences, and thus character, even once they were released. However, even if consent could be reliably granted for nano-neurological rehabilitative interventions – which I have argued it cannot – a new ethical concern emerges when considering use of nano-technology in the name of rehabilitation; namely, do we really want to permanently neurologically alter citizens into a certain idea of what it is to be a “good” citizen? Up to recently, persons who violate the law are allowed to remain the sort of person they are (even if that person was a pedophile), although the space within which they are allowed to be that person is limited to a jail or prison. And after an offender served their time, persons are released to continue to pursue their preferences. Alternatively, persons might be released from prison if our idea of moral standards changes and their desires are no longer deemed criminal (e.g., consider what happens with political prisoners when there is a regime change). Before permanently altering offenders based upon a current legal and moral code, we will also need to claim that the code to which we mold their new character is in a sense “timeless”⁸².

Traditional rehabilitative programming attempts to change preferences for illegal behavior. Often such programming tries to get offenders to adopt different second order preferences, via therapy, or attempts to change the offender's first order preferences, often by attempting to change his environment. For example, job training or GED programs might be seen as attempting to encourage offenders to value being law-abiding or responsible, and to diminish a criminal's preference for stealing things by helping them earn money to buy them. Drug rehabilitation programming usually commonly consists in therapy (individual or group); drug testing and skills learning programs. Rarely, there is a pharmacological component such as methadone maintenance, but drugs are not usually given as a form of treatment for substance abuse.

In both of these examples an offender may resist the effects of such programming if they really wish to. That is, an offender could continue to value theft or drug use despite the programming, and continue such behavior if released from custody. However, this is not the case where castration serves as rehabilitative programming. With castration – especially nano-castration – there is no choice for the offender to make their second-order sexual preferences effective after the castration occurs because the first order sexual preferences are directly removed. And again, if it became possible to directly inhibit or implant second-order desires, this outcome is even more severe.

⁸² A related matter is the ethical question of authority and regulation: who gets to decide which prisoners are eligible for alteration? How serious will the antisocial desires have to be to deserve alteration? Further, if state or federal legislature(s) mandates alteration of certain classes of offenders, judges and juries are still left with the task of categorizing the offenders. Such decisions can be biased, as we have seen with the historically racially-biased system of applying the death penalty.

Consider the following example. James is the sort of character who, once his mind is made up, nothing can change it. He has decided that short people – adults less than 5 feet tall – literally have no reason to live. Hence, he has decided to dedicate his life to killing short people.

Jane, on the other hand, can be talked into anything. Indeed, James talks her into killing Jonah, who is 4'11". Both are convicted of first degree murder. As a part of their punishment, the court requires that they submit to "aggression-elimination" surgery, which in most cases effectively reduces violent recidivism rates to almost zero, before they are released after each serving their 14 year prison sentences.

Now, James would have continued to kill short people once he was released. (Remember, he is just that hard-headed sort of person who is determined to let his hatred for short people guide his acts.) Thus, the surgery does indeed alter James' character in a way that any traditional sort of rehabilitative programming, which respected autonomy, would not.

Similarly, Jane's character is also changed by the surgery: Jane may, or may not have recidivated depending upon what sort of crowd she fell in with after being released. Her wishy-washy character would be fundamentally changed by the surgery, at least with regard to aggressive acts. Thus in both James and Jane nanotechnology would have permanently altered second-order preferences, or a character trait, that would otherwise be "firm and unchanging". Both James' and Jane's autonomy was breached.

One might argue that it isn't such a bad thing to eliminate these persons' ability to choose to kill, or that they "gave up" the right to maintain a certain type of character when they committed a murder. First, I fundamentally disagree: one never gives up their right to be a certain sort of person, even if they give up the right to live freely amongst others *as* that sort of person.

Second, just as any sort of castration impacts all sexual expression, not just criminal sexual expression, the sort of surgery described above impacts all use of aggression – even when, let's say, one needs to be aggressive to defend one's life. The cases of James and Jane both violate Bomann-Larsen's "appropriateness-constraint". Indeed, at this point I might offer the following conclusion regarding this constraint: change to an *agent's character* is never an appropriate or proportional response to a wrongful *act*, and thus no nano-neurological intervention will ever meet this constraint. An act is a behavior within a particular context in a single time-slice. An autonomous agent, or a character, is "bigger" than a single act, or even multiple acts: It is a self.

6. Conclusion

The criminal law's aim of social order, and punishment of wrongful acts, is achieved via certain "principles of punishment", which traditionally guide the structure of criminal offenses and punishment. The argument above has shown that these principles do not justify the use of at least two of the sentencing policies that might be enabled by nanotechnology; nano-tracking and nano-castration, especially in light of the ethical concerns they entail. Nano-tracking is worrying due to its permanency; and any sort of nano-neuroscientific intervention potentially violates an offender's autonomy.

References

- Andenaes J. (1966). "The General Preventive Effects of Punishment". *University of Pennsylvania Law Review*, 114.
- Aristotle (1985). *The Nicomachean Ethics*. Indianapolis.
- Becker G.S. (1968). "Crime and Punishment: An economic approach". *Journal of Political Economy*, 78.
- Bentham J. (1996). *An introduction to the principles of morals and legislation*. Burns J.H., H.L.A. Hart (eds.), with a new introduction by Rosen F. and an interpretive essay by Hart H.L.A., Oxford;
- Bomann-Larsen L. (2011), "Voluntary Rehabilitation? On Neurotechnological Behavioural Treatment, Valid Consent and (In)appropriate Offers". *Neuroethics*.
- Bradley G.V. (1999). "Retribution and the Secondary Aims of Punishment". *The American Journal of Jurisprudence*.
- Brady B. (2008). "Prisoners 'to be chipped like dogs'". *The Independent*. United Kingdom.
- Cullen F.T., P. Gendreau (2000). "Assessing Correctional Rehabilitation: Policy, Practice, and Prospects". In *D. o. Justice* (ed.), 3.
- Duff R.A. (1990). *Intention, Agency & Criminal Liability*. Oxford.
- Dworkin G. (1988). *The Theory and Practice of Autonomy*. Cambridge.
- Gainey R.R., B.K. Payne, M. O'Toole. (2000). "Relationships Between Time in Jail, Time on Electronic Monitoring, and Recidivism: An Event History Analysis of a Jail-Based Program". *Justice Quarterly*, 17.
- Greeley H.T. (2008). "Neuroscience and Criminal Justice: Not Responsibility but Treatment". *Kansas Law Review*, 56.
- Green A. (2009). "More States Use GPS to Track Abusers The New York Times". *Newburyport*.
- Grunwald A. (2005). "Nanotechnology - A New Field of Ethical Inquiry?". *Science and Engineering Ethics*, 11.
- Harrison K. (2007). "The High-Risk Sex Offender Strategy in England and Wales: Is Chemical Castration an Option?". *The Howard Journal of Criminal Justice*, 46.
- Hart H. (1968). *Punishment and Responsibility: Essays in the Philosophy of Law*. Oxford.
- Hinson Z. (2008). "Conversation: GPS Monitoring of Domestic Violence Offenders: GPS Monitoring and Constitutional Rights". *Harvard Civil Rights - Civil Liberties Law Review*.
- Jain K. (2006). "Role of Nanotechnology in Developing New Therapies for Diseases of the Nervous System". *Nanomedicine*, 1.
- Johnstone G., D. Van Ness (2006). *Handbook of Restorative Justice*. UK.
- Macready N. (1996). "Chemical Castration for Paedophiles Approved". *BMJ*, 312, 1.
- Mainprize S. (1992). "Electronic Monitoring in corrections: Assessing cost effectiveness and the potential for widening the net of social control". *Canadian Journal of Criminology*, 1.

- Mendes S.M. (2004). “Certainty, Severity, and Their Relative Deterrent Effects: Questioning the Implications of the Role of Risk in Criminal Deterrence Policy”. *The Policy Studies Journal*, 32.
- Mendes S.M., M.M. McDonald (2001). “Putting the Severity of Punishment Back in the Deterrence Package”. *Policy Studies Journal*, 29.
- Millholon M. (2008). “Jindal Signs Chemical Castration Bill”. *Louisiana Advocate*, Louisiana.
- Model Penal Code Proposed Official Draft 1962.
- Moore M.S. (1988). “The Moral Worth of Retribution”, in Schoeman F. (ed.). *Responsibility, Character and the Emotions: New Essays in Moral Psychology*.
- Nagin D.S. (1998). “Criminal Deterrence Research at the Outset of the Twenty-First Century”. *Crime and Justice*, 23.
- Padgett K.G.W.D. Bales, T.G. Blomberg (2006). *Under Surveillance: An Empirical Test of the Effectiveness and Consequences of Electronic Monitoring*.
- Raab S. (1991). “Electronic Monitoring Is Planned for Detainees”. *The New York Times*. New York Region.
- Rickert S.E. (2007). “Taking The NanoPulse - My RFID Tag Is Smaller Than Your RFID Tag”. *Industry Week*.
- Rosenberg I.B. (2007). “Involuntary Endogenous RFID Compliance Monitoring as a Condition of Federal Supervised Release - Chips Ahoy?”. *Yale Journal of Law & Technology*.
- Sifferd K.L. (2008). “Nanotechnology and the Attribution of Responsibility”. *Nanotechnology Law and Business*, 5.
- Silva G.A. (2006). “Neuroscience Nanotechnology: Progress, Opportunities and Challenges”. *Nature Neuroscience*, 7.
- Smith K.L. (1998). “Making Pedophiles Take Their Medicine: California’s Chemical Castration Law”. *The Buffalo Public Interest Law Journal*.
- Steen S., R. Bandy (2007). “When the policy becomes the problem: Criminal justice in the new millennium”. *Punishment and Society*, 9.
- Stephan J.J. (2004). *State Prison Expenditures*. U.S. Department of Justice.
- Tonry M. (1996). *Sentencing Matters*.
- West E. (2008). “Napa County Department of Corrections Home Detention and Work Furlough Programs”. *Napa County Board of Supervisors*, 4.
- Wolfe J. (2005). “Nano Noses Into RFID”. *Forbes*.

Biobanks, Patents & Intellectual Property Rights (IPR): A Comparative Study of the US & Europe from the Perspective of India

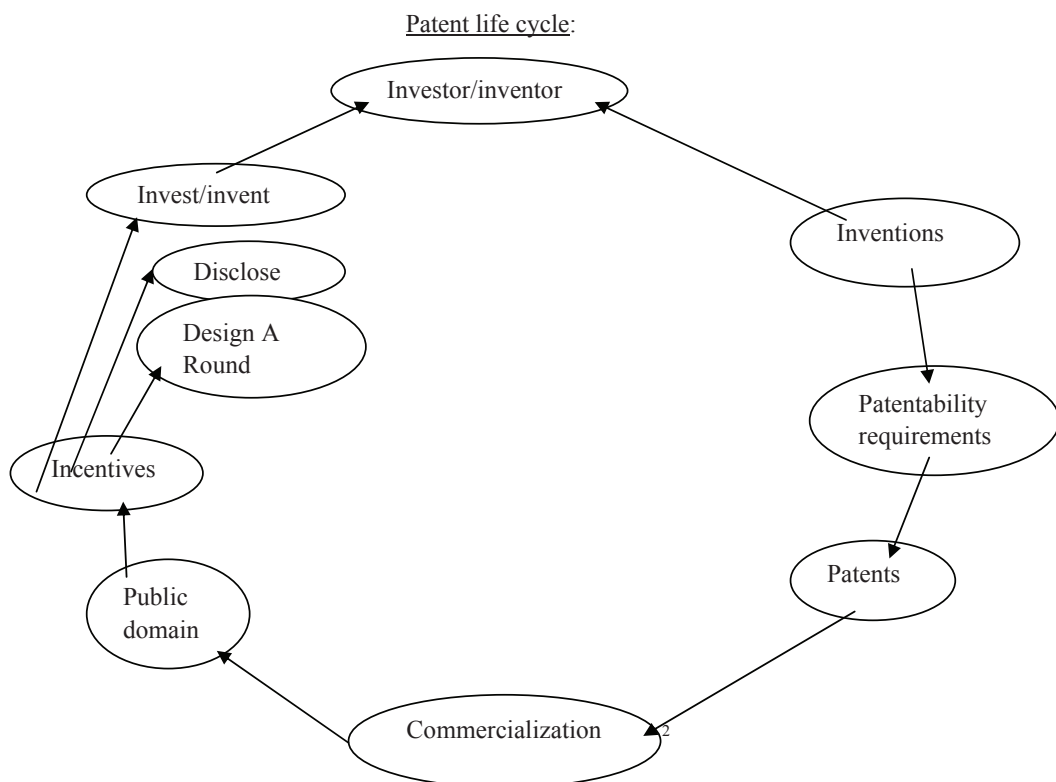
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Abstract: Much of the current activity of biobanks focuses on the identification and subsequent patenting of genes and segments of DNA that might be useful in diagnostic testing, gene therapy, and drug development. With gene patents potentially worth over a billion dollars a year to the patent holder, it is no wonder that companies are willing to pay hefty amounts for access to biobank research on particular disorders. Yet gene patenting poses potential harm to the tissue source, the health care system, and the research enterprise. The so-called Indian 'Bio-Diversity Act', which came into force in 2002, stipulates that permission from the Indian Government is required in order to use any rare species or valuable material which is found in any part of the Indian territory for research purposes. It also stipulates that a certain percentage of benefits accruing from such use should be made over to India. India is also a signatory to the Convention on Biological Diversity (CBD) and is thus bound to abide by the principles set forth therein. The CBD provides for the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of use of biological resources. Article 1 Section 8, Clause 8 of the US Constitution gives Congress the power to promote the progress of science and the useful arts by awarding exclusive rights for a certain period of time to authors and inventors on their respective works and discoveries. In furtherance of the powers granted to it by the Constitution, the Congress enacted the Patent Law which was codified under Title 35 of the US Code. Thus, under the US law, includes genes, genetically modified unicellular and multi-cellular organisms, animals and plants are patentable as is gene therapy. In Europe, patents are covered by Article 52 of the European Patent Convention (EPC). As of 2005 in Europe there were 239 patents, of which 15 were in the biotechnology field, 9 were medical bio-technology patents and 5 genetic patents. Article 52 states that patents shall be granted for any inventions which are susceptible of industrial application. They shall be new and involve an inventive step and indicates which inventions are not patentable.

Contents: 1. Introduction - 2. Intellectual Property, Patents and Biobanks - 2.1. International and Regional Perspectives - 2.2. IPR, Patents and Biobanks in developing countries - 3. Comparative Study of India, Europe and the USA - 4. Conclusion - References

1. Introduction

Patent Law is a division of the larger field of law known as Intellectual Property Law and it is recognized that some types of intellectual property should be granted legal protection. A patent is a contract between the government and an inventor under which, in exchange for the inventor's complete disclosure of the invention to the public, the government grants the inventor the exclusive right to prohibit others from making, using, selling, or offering for sale the claimed invention for a limited period of time, in general for the twenty years after filing of the patent application¹.



An invention is patentable only if it satisfies the patentability requirements of patentable subject-matter, usefulness, novelty, non-obviousness and specification. The requirements work like filters in tandem³.

The last few years have witnessed immense expansion in the collection and processing of human biological samples and related data. Biobanks – huge repositories of

¹ Zekos G., Bsc. (Eco), JD, LL.M., Ph.D., Attorney at Law-Economist.

² Kankanala K.C. (2007), *Genetic Patent Law and Strategy*.

³ Kankanala K.C. (2005), *Complications in patenting biotech inventions: A peek at US Law*.

human biological specimens – are of strategic importance for genetic research, clinical care, and future treatment. However, biobanks are facing many major ethical, legal, and governmental challenges related to the issues of informed consent, privacy, ownership, commercialization, and harmonization. Biobanks are considered to be an important resource for research issues as they are regarded as archives or repositories mainly formed by libraries of biological content, drawn from individuals or species. Information is connected to content and represented by its medium, in the form of data, and constitutes an intangible, priceless good. Questions relating to intellectual or physical property are extremely complicated due to uncertainty either because there are no rules or the rules that there are do not regulate these questions adequately. The lack of a unique reference frame allows the private sector, driven by strong economic interests, to privatize data and information to the detriment of the common good, as is the case with the flourishing market of cord blood banks, where the debate about stem cells is exploited for profit making purposes. By means of several recent initiatives, biomedical research is attempting to make its data freely available by adopting an open source model, thus stimulating innovation and further research. We will analyze those issues connected to commons and to intellectual commons regarding the concepts of private ownership of data and biological materials, by tracing the path between the definitions of “biobank”. This will identify two main issues, the first stemming from literature, the second from regulations. We will pass through channels regarding legal aspects (as physical and intellectual property), touch on the concept of “commons” compared to the concept of private ownership of biological materials, the privacy of patients and information, to reach the question of intellectual property and the difference between finding and invention for the purposes of patenting.

A biobank is a cryogenic storage facility used to archive biological samples for use in research and experiments. Ranging in size from individual refrigerators to warehouses, biobanks are maintained by institutions such as hospitals, universities, non-profit organizations, and pharmaceutical companies. Biobanks are generally maintained for the conservation of species, flora, fauna and genetically modified plants etc.⁴

2. Intellectual Property, Patents and Biobanks

The World Intellectual Property Organization (WIPO) has made a tremendous contribution to development in the areas of genetic resources, traditional knowledge and folklore and their bio-prospecting in a sustainable manner through the route, among others, of intellectual property right. At the same time, the contribution of local and indigenous communities to the conservation and development of genetic resources for food and health cannot be ignored. To state that the entire gamut of issues relating to genetic resources has economic implications is to state the obvious. Whereas developing countries, by and large, possess rich biological diversity and plant genetic resources, developed countries have the technological resources and wherewithal to exploit these natu-

⁴ Silberman S. (2010), *The flesh files*.

ral resources commercially. The issue thus becomes one of sharing the benefits accruing from such exploitation. The common good of mankind should therefore act as the catalyst for achieving an equitable distribution of benefits across the world. In this endeavour it appears that the WIPO, as an ideal and a neutral platform, has both the credibility and the ability to harmonize the very complex issues involving the aim of ensuring justice for all⁵. The biological and the genetic resources which has been traced its cherished value in this twenty first century has deepened its characteristics⁶. In fact, it has been so incisive that even the mystery of the human genome has been unravelled. The new millennium, therefore, poses serious challenges to the international legal community, pressing it to set new international legal standards for tackling the problems of intellectual property protection thrown open by technological developments⁷. Functioning under the biobank has been formulated through a two way process. Firstly inlet research, secondly outlet conservation. Inlet research helps preservation by establishing clones, genes, etc. of the species and thus protecting them from creating an imbalance in the lifecycle. Outlet preservation means preservation by establishing research centres or sanctuaries, etc. There are certain principles that are certified. One is the traditional principle whereby knowledge in the public domain is for free exploitation, without any respect or concern being shown for efforts made by communities to preserve and promote same. New technological developments, particularly in biotechnology, clearly demonstrate the significance and usefulness of traditional knowledge for the development of new products of commercial importance. The need to protect traditional knowledge has captured the attention of the international community only recently, but standard setting has been left up to national governments. The absence of international standards, however, gives rise to serious concerns with regard to the protection of traditional knowledge and the custodians of such knowledge enjoying the benefits of new technology⁸. A biobank is also a repository for bio-materials from a representative portion of the human population. Biobanks act as vaults containing intricate detailed information about individuals from whom biological materials have been collected. Data collection and proper cataloguing are essential to the success of a biobank. Research and development in the field of establishing biobanks or in the field of bio-technology has opened up new vistas in the regime of IPR. Serious efforts are being made to increase the number of inventions and of patent applications. Biobanks, just like other DNA databases, must carefully store and document access to samples and donor information. Samples must be maintained reliably with minimal deterioration over time and must be protected from physical damage, both accidental and intentional. The registration of each sample entering and exiting the system is centrally stored, usually on a computer-based system that can be backed up frequently⁹.

⁵ Tripathi K.S. (2003), "Intellectual Property and Genetic Resources. Traditional Knowledge & Folklore: International, National & Regional Perspectives, Trends & Strategies".

⁶ <<http://www.SSRN.com>>

⁷ <<http://www.freeessay.com>>

⁸ Nwabueze R.N. (2007), *Biotechnology & the challenge of property: Property rights in Dead bodies*.

⁹ Macleod A.K., D.C. Liewald, M.M. Mcgilchrist, A.D. Morris, S.M. Kerr, D.J. Porteous (2009), *Some principles & practices of genetic bio banking studies*.

2.1. International & Regional Perspectives

Historically, many social communities have survived thanks to their traditional knowledge base. Many local and indigenous communities in Asian countries meet their basic needs from the products they manufacture and sell based on their traditional knowledge. Even today maintenance of their health is based on traditional medicines derived from plants and other natural products. New technology and new uses for traditional medicines derived from plants and other natural products has been developed. This development is today one of the major threats to the survival of many of these communities. Modern cultural industries (printing, film, records) as well as the manufacturing industries (textiles, handicrafts, pharmaceuticals, seeds, etc.) now commercially exploit traditional knowledge-based products using new technology without getting permission to do so from communities or sharing their profits with them. New products or new uses for existing products based on traditional knowledge can now be created using technological developments in the field of bio-technology. This has been proved beyond doubt, particularly in the field of medicines, agriculture, etc.

Bio-prospecting helps scientists in modern pharmaceutical research laboratories to obtain the know-how on developing new products or finding new uses for existing products. Similarly, traditional designs of articles are reproduced by modern industries to be applied in consumer products. The development of new products or new uses for existing products enables industries to obtain protection for these products through IP laws. One of the concerns of the developing world is that the process of globalization is threatening to appropriate elements of this collective knowledge for the commercial profit of a few. Urgent action is needed to protect these fragile knowledge systems through national policies and international understanding linked to IPR, while providing for their development and proper use for the benefit of their custodians¹⁰. Those provisions of the CBD which are aimed at recognition of and respect for the traditional knowledge of local and indigenous communities in genetic materials and at sharing the benefits accrued through their use seems to be the first express international commitment.

Under Article 8(j) of the CBD: “Each contracting party shall, as far as, possible and as appropriate, subject to its national legislation, respect, preserve, and maintain the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”. However, many signatory states have yet to bring in legislation putting the provisions of the Convention into effect¹¹.

The TRIPS part of the Marrakesh Agreement was signed by various nations belonging to the WTO. The Agreement obliges signatories to treat all fields of technology equally in the granting of patents. However, the Agreement allows signatories to ex-

¹⁰ Sharma S.K. (2005), *IPR and genetic resources: international, regional and national perspectives, trends and strategies*.

¹¹ Edited by Veena: Biotech Patent.

clude certain inventions from patenting on the grounds of protecting public order or morality, animal or plant life or health and the environment¹². It also allows signatories to exclude medical methods, plants or animals except micro-organisms and essential biological processes from patenting¹³. Signatory states can configure their patentability filters only after fulfilling the basic requirements laid down in the TRIPS.

2.2. IPR, Patent & Biobank in developing countries

Technological advances and other innovations have made it feasible for developing nations to establish biobanks – repositories of human biological samples linked with data from individuals. A global consortium of biobanks offering “accessible and affordable studies in diverse populations” is likely to emerge, permitting “imaginative searches for common and rare genetic and other biological co-relates of global diseases”¹⁴. In India there is certain legislation in this regard such as the 2002 Bio Diversity Act 2002 and India is also a signatory to the CBD. The concept of a biobank related to patent and intellectual property rights may be understood by the following example: permission is required from the Indian Central Government to use a species which is rare in nature and is found within any territorial limit in India. Furthermore, a share in the profits and benefits accruing from such use must be made over to India. There has been much development in India in recent years in the areas of patents, biological diversity and plant genetic resources, etc. India is one of the top sixteen mega-diversity countries in the world, accounting for 7-8% of the earth’s total bio-diversity.

Over 47,000 species of plants and around 89,000 species of animals have already been recorded by the Botanical Survey of India. These results are based on a survey of 65-70% of the total geographical area of the country¹⁵. India is one of the major primary centres of origin but its patents have been revoked. Foreigners obtain patents based on Indian biological materials without acknowledging the source of their knowledge or sharing the benefits. The recently amended Indian patent law contains provisions stipulating the mandatory disclosure of the source, geographical and biological origin of the biological material used in an invention when applying for patents in India. It also stipulates that non-disclosure of same may be grounds for opposition to and revocation of a patent. India is a signatory to the CBD and introduced the Biological Diversity Act in 2002.

The Biological Diversity Act provides for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising from use of the biological resources and associated knowledge. In order to ensure equitable sharing of such benefits, the Act stipulates that there must be prior approval from the National Biodiversity Authority (NBA) before access is permitted. Upon granting approval, the NBA imposes terms and conditions which ensure equitable sharing of bene-

¹² TRIPS agreement, 1994 Article 27 Para 2.

¹³ TRIPS agreement, 1994 Article 27 Para 3.

¹⁴ Sgaier S.K (2007), *Bio banks now feasible in developing nations*.

¹⁵ Ganguly N.K. (2008), “Indian bio banks: concepts & prospects”.

fits. The Act also provides that anybody seeking any kind of intellectual property rights for research based on biological resources obtained from India needs to obtain prior approval from the NBA. The NBA also imposes benefit-sharing conditions. In fact, one of its functions is to take the necessary measures to oppose the grant of IPRs in any country outside India with regard to biological materials and associated knowledge originating in India¹⁶.

The Indian Protection of Plant Varieties and Farmers' Rights Act of 2001 also acknowledges that the conservation, exploration, collection, characterization and evaluation of plant genetic resources for food and agriculture are essential in order to meet the goals of national food security and for the sustainable development of agriculture for the present and future generations. It also acknowledges that plant genetic resources for food and agriculture are the indispensable raw materials for improving crop genetics. The concept of effective benefit sharing between the provider and the recipient of plant genetic resources is a fundamental part of the Act. How much of the benefit is shared depends on the extent and nature of the use of genetic material in the development of a variety and the commercial use and sale of the variety. To make this meaningful, a provision has been included for mandatory disclosure of the geographical source of the genetic material and information relating to the contribution, if any, of the farming community in developing the variety. The protection provided to a plant variety cultivated by a grower can be revoked for failure to disclose such information or for its wrongful disclosure¹⁷. The 1999 Geographical Indication of Goods (Registration and Protection) Act represents another step taken by India. The Act primarily intends to protect the valuable geographical indications of India. Protection under the Act is available only to the geographical indication registered under the Act and to authorized users. The Act permits any association of persons or products or any association of persons or producers or any organization of authorities established by law representing the interest of the producers of goods to register a geographical indication. It may be argued that the holders of the traditional knowledge in goods produced thus and sold under the geographical indication can register and protect their rights under this law.

3. Comparative Study of India, Europe and the USA

Several distinctions may be made between India, Europe and the USA in relation to IPR, patents and biobanks. There is certain data on the basis of which a comparative study of the three can be made:

EUROPE

Art. 52 of the EPC states that patents shall be granted for any inventions which are susceptible of industrial application. They shall be new and involve an inventive step and indicate inventions which are not patentable. The European Council promulgated the

¹⁶ Andrews L.B. (2005), "Harnessing the benefits of biobanks".

¹⁷ Chandrashekran S., S. Vasudev (2002), *The Indian plant variety protection Act beneficiaries: the Indian farmer or the corporate seed company?*

bio technology directive in 1998, although Rule 23(b) provides that in relation to European Patent applications for biotech patents, the relevant provisions of the Convention will be applied and interpreted in accordance with the provisions of chapter VI of the implementation regulation¹⁸.

Unicellular Organisms

Article 53(b) of the EPC excludes plant and animal varieties and essential biological processes from the scope of patent protection but provides an exemption for the patenting of microbiological products or processes. T356/193 states that micro-organisms are patentable as products of microbiological processes. Rule 23C of the Regulation provides that plants/animals are patentable if the technical feasibility of the invention is not confined to a particular plant/animal variety. Genetically modified plants/animals are held to be patentable as they fall outside the purview of the animal/plant variety.

USA

Gene sequences and gene probes are patentable in the USA: as there has been no judicial scrutiny of patentable subject matter relating to gene/DNA sequences, the interpretation of the USPTO stands good. The USPTO has extended patent protection to isolated DNA, RNA and protein sequences, stating that protein sequences are new compositions of matter resulting from human intervention as opposed to naturally occurring products which are not patentable. The exclusion of any product of nature is not a hurdle to patenting gene or DNA sequences because isolated and purified sequences are not naturally existing and contain only the regions of naturally existing DNA that code for proteins. The number of patents over gene sequences increased after NIH filed patent applications over cDNA sequences and ESTS in the early 1990's¹⁹. Organisations like Human Genome Sciences, Incyte Pharmaceuticals, Millennium Pharmaceuticals and Celera Genomics etc have filed and acquired hundreds of patents over DNA sequences²⁰.

Unicellular Organisms

Questions relating to the patentability of unicellular organisms first came before the US Supreme Court in the *Funk Brothers Seed Co. v Kalo Inoculant Co.* case. This case involved an invention related to a mixed culture of rhizobium bacteria capable of simultaneously inoculating the seeds of plants belonging to several cross inoculation groups. The Court held that the mere aggregation of species fell short of invention within the meaning of the patent statute because the combination of species produced no new bacteria and no change in the 6 species of bacteria. As there was no change in the species, the court stated that the qualities of the non-inhibitive strains were the work of nature and therefore not patentable subject products of nature²¹.

Chakrabarty v. Diamond is considered a landmark case. It was held that everything under the sun made by man is patentable. The decision cleared up all doubts and

¹⁸ UK bio bank ethics and governance framework: UK Bio Bank October 2007.

¹⁹ Zhang S. (2004), "Proposing Resolutions to the Insufficient Gene Patent System".

²⁰ Stokes G. (2000), *Patent Applications of Genetic Sequences on the Up*.

²¹ Kankanala K.C. (2005).

opened the gates to the patentability of bio-tech inventions. Chakrabarty's invention involved genetically modified pseudomonas bacterium capable of degrading four different oil components that could be transferred to and maintained stably by a single pseudomonas bacterium, which by itself had no capacity for degrading oil. Chakrabarty's patent claims were of 3 types: *firstly* process claims for the method of producing the bacteria; *secondly* claims for an inoculum comprising a carrier material floating on water such as straw and the new bacteria and *thirdly* claims to the bacteria itself²².

INDIA

In India there is a bar on the patenting of any living things which occur in Nature²³. The Indian Patent Act provides that plants and animals in whole or in part including seeds, varieties, species and essential biological processes for the production/ propagation of plants and animals are not patentable²⁴. However the Act allows for micro-organisms and micro-biological processes.

The Calcutta High Court diverted from the position of the Controller of Patents, holding that a living micro-organism constitutes patentable subject matter as a manufacture²⁵. Thus genetically modified micro-organisms are patentable as per the statute and case law.

Genetically modified multi-cellular organisms including plants, animals, human beings and their parts are not patentable in India. Under Section 3 of the Manual of Patent Practice and Procedure, biological material such as recombinant DNA, plasmids and manufactures are patentable if they are produced by substantive human intervention²⁶. Human cloning, animal processes for modifying germ lines and genetic identification of human beings/ animals are not patentable as they run contrary to public order and morality²⁷. The use of animal/ human embryos is also non-patentable.

Indian Assignees Patent Filing:

Year	All Patents	Bio Patents	Medical Bio technology	Genetic
1995	29	2	2	0
1996	53	4	3	0
1997	82	9	7	2
1998	98	13	10	3
1999	109	13	8	2
2000	178	32	27	4
2001	272	39	28	6
2002	321	11	9	8

²² Kankanala, K.C. (2007).

²³ Indian Patent Act 1970 Section 3(3), Amended in 1999, 2002, 2005.

²⁴ Indian Patent Act 1970 section 3(J), Amended in 1999, 2002, 2005.

²⁵ Dimminaco A.G.V. (2002), "Controller General of Patents Design & Trademarks".

²⁶ Manual Patent, Practice & procedure, 2005.

²⁷ Indian Patent Act 1970, Section 3 (c), Amended in 1999, 2002, 2005.

PATENTABILITY OF GENE RELATED SUBJECT
MATTER IN THE USA, INDIA AND EUROPE:

Subject Matter	USA	Country EPC	India
Genes	Patentable	Patentable	Patentable
Genetically Modified Unicellular Organisms	Patentable	Patentable	Patentable
Genetically Modified Multicellular Organisms	Patentable	Patentable	Non Patentable
Genetically Modified Animals (Excluding Humans)	Patentable	Non Patentable	Non Patentable (Except Mammals)
Genetically Modified Plants	Patentable	Patentable	Non Patentable
Genetically Modified Humans	Non Patentable	Non Patentable	Non Patentable
Gene Therapy	Patentable	Non Patentable	Non Patentable

4. Conclusion

The invention of biobanks will revolutionize the health care industry by configuring the causative factors that ail the human body. Biobanks can be established without supervision, even without the knowledge of those people whose tissues are being used. Yet the practice of biobanking raises profound ethical and legal questions with regard to the circumstances under which such banks are established and how the benefits of the bank are harnessed. People participate in health research in order to further develop medical diagnostics and treatments. Patenting genes discovered in biobank tissues can thwart that goal, however. Some gene patent holders have used their monopoly power to actually prevent other researchers from undertaking research on the disease that their gene patent covers. Much of the current activity of biobanks focuses on the identification – and subsequent patenting – of genes and segments of DNA that might be useful in diagnostic testing, gene therapy, and drug development. With gene patents potentially worth over billions of dollars a year to the patent holder²⁸ it is no wonder that companies are willing to pay sums such as \$200 million for access to biobank research on particular disorders.²⁹ Yet gene patenting poses potential harms to the tissue source, health care system and research enterprise. These problems are sufficiently troubling that many international societies oppose gene patenting as a threat to medical advances and patient care. Consequently, tissue sources should be informed in advance of any re-

²⁸ Thomas S.M (1996), *Ownership of the Human Genome*.

²⁹ Kunzig R. (1998), *Blood of the Vikings*.

search on their tissue, about whether or not genes discovered in their tissues (or related products created on the basis of this genetic information) will be patented, how the patent will be licensed, and what the impact of the patents is likely to be on health research and care. This is material information because when a gene is discovered in a biobank tissue sample and patented, the gene patent holder can charge whatever it likes for a diagnostic test for mutations in that gene (or any other use of the gene).

A patent holder can prohibit anyone else from performing the diagnostic test for the gene, and instead require all doctors to send the patient's sample for testing to the patent holders own lab, which may be in another state or even another country. In fact, the tissue source whose gene is patented could find that he cannot afford the test or treatment created with his own gene or that he cannot get access to a genetic diagnostic test for family members because the gene patent holder is restricting who may perform the test.

Due to its multiple uses in the bio-technology age, human tissue is being gathered and stored in repositories known as biobanks. Some biobanks have been created indirectly. Biobanks collect and store human bio-specimens, playing a vital role in the development of new drugs and diagnostics. In recent years, large population based biobanks have been established which monitor the health status of the participants over time, assessing the natural occurrence and progression of common diseases. However, for the purposes of the Directive, inventions which are susceptible of industrial application shall be patentable if they concern an isolated element of the human body or are produced by a technical process, even if the structure of this element is identical to that of a natural element; and the Directive assumes that the rights conferred by a patent do not extend to the human body or its elements in their natural environment. Therefore an invention derived from a biological sample is patentable if is the result of technical processes used to identify, purify, classify, and reproduce it outside the human body, techniques which human beings alone are capable of carrying out and which nature is unable to accomplish by itself. The patenting of such an invention is subject to the classical criteria of patentability, namely: novelty, inventive step, and industrial application³⁰ and in these cases the Directive demands that the industrial application (utility) must be disclosed when the patent application is filed. Inventions are subject not only to these requirements but also to other controls, known as traditional in patent law, because they are classical exceptions in it. *Firstly*, that publication or exploitation does not run contrary to public order or morality (Article 53 EPC) and *secondly* that the subject-matter is not a plant or animal variety or an essential biological process for the production of plants and animals (Article 53(b) of the EPC).

³⁰ Uranga A.M. (1997), *Legal Protection Of Bio Technological Innovations, Special consideration to criminal protection.*

After adoption of Directive 98/44/EC, a list of non-patentable inventions was drawn up in order to provide the courts and national patent offices with a guide to interpreting the terms public order and morality. This list, however, is not exhaustive. It excludes from patentability:

- Processes for cloning human beings;
- Processes for modifying the germ line genetic identity of human beings;
- Uses of human embryos for industrial or commercial purposes;
- Processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to mankind or to the animals resulting from such processes.

There is thus no mention of the non-patentability of a product derived from a biological sample. Such a sample is patentable provided it meets the requirements of patentability and does not run contrary to public order and morality and its subject-matter is not a plant, animal variety or essential biological process for the production of plants and animals.

Nonetheless, a patent does not allow an owner to prohibit third parties from exploiting the invention for industrial and commercial purposes and consequently a patent right shall not substitute or render ineffective national, European or international regulations determining limits or prohibitions or organizing checks on research and commercialisation of the results, particularly in terms of requirements for public health, security, the environment, animal protection, the preservation of genetic diversity and respect for certain ethical rules.

Thus the collection of biological samples for bio-medical research purposes shall be carried out only with the previous and express consent of the source subject. If there is no opposition from the source subject, the biological samples can be used for bio-medical research even if they were collected with the purposes. In that case, the sample shall be rendered anonymous³¹. Thus from a future perspective it can be said that biobanks are essential, especially with regard to the advancement of developing nations and to the protection of their natural heritages.

India is planning to establish a national biobank or National Repository (NR). It is an initiative which is open to ethical, legal and social scrutiny. The initial idea was to provide a centralized repository for the bio-specimens and health data which was randomly and unsystematically collected and stored at various research centres, including those of universities, public and private hospitals and research institutes. Such institutions, databases and other biomedical data collections are hard to enumerate and map, let alone describe in brief. It is however feasible to describe the process through which much of the data has been obtained. This chapter describes how biological specimens and health data is gathered. It is generally conducted through two processes: first, through genetic epidemiological and carrier-screening programmes in community set-ups and second through individuals and patients in hospital set-ups. At community

³¹ Uranga A.M. (1998), *Outstanding legal and ethical issues on biobanks: an overview on the regulations of member states of the EuroBioBank project.*

level, it is the population geneticist, local hospitals and physical anthropologists who are involved in data generation; at hospital level, it is individual patients who provide data through undergoing testing or donating tissue. Investment in India's proposed national biobank initiative is expected to come under great scrutiny, owing to the enormous social, economic and health care disparities and a lack of well-defined and stringent regulatory mechanisms for the conduct of biomedical research. In this paper an attempt is made to stimulate discussion on common bioethical issues, such as informed consent, confidentiality, benefit sharing and public trust by referring to the views and practices of researchers and community leaders themselves. The bioethical issues discussed here are considered to be vital in the field of genomics in India from a community perspective based on an anthropological study³².

³² The Indian genomic bio bank initiative and emerging bioethical issues : a community based perspective: A Study of Economic & Social Research Council.

References

- Andrews L.B. (2007). "Harnessing the benefits of bio banks". *The Journal of Law, Medicine & Ethics*, 33.
- Chandrashekrans S., S. Vasudev (2002). "The Indian plant variety protection Act Beneficiaries: the Indian farmer or the corporate seed company?". *Journal for Intellectual Property Rights*, 7.
- Dimminaco A.G.V. (2002). *Controller General of Patents Design & Trademarks. Manual of Patent Practice & Procedure* © Controller General of Patents, Designs & Trade Marks, India.
- Ganguly N.K. (2008). "Indian bio bank: concepts & prospects". *Research Report: July 2007 – December 2008*.
- Kankanala K.C. (2007). *Genetic patent law & Strategy*. Manupatra Information Solutions Pvt. LTD, Noida.
- Kankanala K.C. (2005). *Complications in patenting biotech inventions: A peek at US Law*. San Francisco.
- Kunzig R. (1998). *Blood of the Vikings*. New York (documentary).
- MacLeod A.K., D.C. Liewald, M.M. Mcgilchrist, A.D. Morris, S.M. Kerr, D.J. Porteous (2008). *Some principles & practices of genetic bio banking studies*.
- Nwabueze R.N. (2007). *Biotechnology & the challenge of property: Property rights in Dead bodies*. Ashgate Publishers, Aldershot.
- Sgaier S.K. (2007). *Bio banks now feasible in developing nation*. AAAS.
- Sharma S.K. (2005). *IPR and genetic resources: International, regional and national perspectives, trends and strategies*. Universal Publications, Delhi.
- Silberman S. (2010). "The flesh files". *Wired Magazine*. California.
- Stokes G. (2000). *Patent Applications of Genetic sequences on the up*. Thomson Scientific, London.
- "The Indian genomic bio bank initiative and emerging bioethical issues: a community based perspective: A Study of Economic & Social Research Council" (2008). Routledge, Taylor & Francis Group.
- Thomas S.M. (1996). *Ownership of the Human Genome*. Nature Publishing Group, Sussex.
- Tripathi K.S. (2003). "Intellectual Property and Genetic Resources, Traditional Knowledge & Folklore: International, National & Regional Perspectives, Trends & Strategies". *WIPO Inter-Regional Seminar, Isfahan (Iran), 14 July 2003*.
- "UK bio bank ethics & governance framework" (2007). *UK Bio Bank*, 3.
- Uranga A.M. (2002). *Legal protection of bio technological innovations*. Rumagraf, Madrid.
- Zhang S. (2004). "Proposing Resolutions to the insufficient Gene Patent System". *Santa Clara Computer & High Technology. L.J.*, 20.

Indian Patent Act 1970 Section 3(3), Amended in 1999, 2002, 2005.

Indian Patent Act 1970 section 3(J), Amended in 1999, 2002, 2005.

Manual Patent, Practice & procedure, 2005.

Indian Patent Act 1970, Section 3 (c), Amended in 1999, 2002, 2005.

TRIPS Agreement, 1994 Article 27 Para 2

TRIPS Agreement, 1994 Article 27 Para 3

[Online] <<http://www.SSRN.com>>.

[Online] <[http:// www.freessay.com](http://www.freessay.com)>.

Cryopreservation of Embryos: The Italian Situation in a European Perspective

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Abstract: In Italy, cryopreservation of embryos is regulated by Law 19 February 2004, n. 40. Article 14 prohibited cryopreservation of the embryos created during IVF, but the Constitutional Court declared this provision unconstitutional for not stating that the transfer of the embryo should not endanger the health of the woman, thus balancing the protection of the embryo with the safeguarding of the woman.

However, even previously the consequences of the refusal of the woman to the implantation had not been clear: there was no specific norm providing for her criminal liability.

This complex issue involves fundamental rights, such as the right to life, the right to have a family, equality between genders and technical aspects, like the destination of the existing embryos, the existence of a time limit for conservation, costs.

National Legislatures in Europe have chosen different levels of protection; in Italy the activity of the Courts is filling the regulatory voids left the Parliament, which has had the difficult task of balancing different fundamental values for the first time.

Contents: 1. Introduction - 2. The Italian Situation - 2.1. Law 19 February 2004, n. 40 and the Referendum - 2.2. The Intervention of the Constitutional Court - 2.3. Guidelines: More than technical regulation - 3. Fundamental Rights Involved and Emerging Difficulties - 4. The European Context: Different Perspectives - 5. Conclusion - References

1. Introduction

Scientific progress has been expanding horizons and possibilities, thus unavoidably increasing for every human being the breadth of choice available. In particular, with the recent developments related to life-science, some choices are imbued with very complex and delicate ethical dilemmas.

The role of the law in dealing with these issues is tough, firstly because the law is subsequent to these new scientific developments, secondly because the legislating body has to face the difficult task of balancing fundamental values.

In particular, the issue of cryopreservation of embryos concerns the very idea of human dignity, but also the right to have a family, the right to health and the right to life itself.

The aim of this paper is to analyse how the Italian Legislature has dealt with this thorny topic by retracing the difficult path of the law that regulates the issue. The final part of the paper will enlarge the perspective by referring to other European Countries and their normative approaches to the subject in question.

2. The Italian Situation

2.1. Law 19 February 2004, n. 40 and the Referendum

The Italian Legislature has dealt with the issue of cryopreservation of stem cells several times; since 2002 many normative rulings have been issued mainly adopting a restrictive approach.

In particular, Law 19 February 2004, n. 40 aims at regulating the issue in relation to embryos. The Act, which contains the “norms applicable to medically assisted procreation”, had a very difficult gestation. It was both submitted to referendum and was the object of many appeals to the Constitutional Court.

As regards referenda in Italy, if a law is perceived not to conform to the Constitution, it can be submitted to popular referendum in order to be repealed. The Radical Party firstly promoted the referendum in order to obtain the repealing of the entire law, collecting more than 1 million signatures¹. In July 2004 a wider agreement among other political parties² was found in relation to a partial reform of the law³. The proposed questions aimed at abrogating the numeric limitation in the production of embryos (which the law had fixed at three), as well as the prohibition of refusing the implantation of the embryo once created, the prohibition of scientific research on the embryo,

¹ The recourse was deposited on 25 March 2004 and on 30 September 2004 the collected signatures were submitted.

² The agreement was across all parties and involved representatives of the left (Democratici di sinistra, Socialisti democratici italiani, Rifondazione Comunista), but also dissenters from the party “La Margherita”, from the Italian Republican Party, from Forza Italia and from Nuovo PSI.

³ Almost 700.000 signatures were presented to the Court of Cassation.

the prohibition of cryopreservation, the prohibition of artificial insemination with the intervention of a donor⁴.

On 13 January 2005 the Constitutional Court rejected the question aiming at the abrogation of the entire law but admitted the questions aiming at a partial repealing, thus authorizing the vote.

The referendum was held on 12 and 13 June 2005 and it was a complete failure, since the requested quorum (50%+1 of citizens with the right to vote) was not reached: only 25,9% of electors voted⁵. But the result of voters was clear: as a matter of fact, of the votes cast between 77,4⁶ and 88,8%⁷ were in favour of the abrogation of the law.

The reasons for such a failure are complex; a survey⁸ showed that 32,7% of Italians did not know about the referendum, and that another 18,5% of citizens did not know the exact content of the questions. In addition to that, actually, in Italy, since 1997, no referendum has reached the quorum⁹ and the percentage of electors has been constantly decreasing in every consultation. As a matter of fact, since that year, referenda have been held on very different topics, from hunting to reform of the judiciary system, from labour to issues relating to party-funding: for this reason it is difficult to explain the failure of the 2005 referendum just by assuming that, in that case, the topic was too technical and difficult for the average citizen. In particular, as regards the number of people voting, the percentage of voters decreased from around 30% in 1997, 49% in 1999 and 32% in 2000 to 25,5% in 2003, 25,9% in 2005 and 23,5% in 2009.

2.2. *The Intervention of the Constitutional Court*

But, after the failure of the referendum, the law came under attack from another side: the Constitutional Court intervened¹⁰ and with the ruling of 8 May 2009, n. 151 declared Paragraphs 2¹¹ and 3 of Article 14 of law n. 40/2004 unconstitutional.

⁴ This prohibition relates to fecundation, but in the Law there was no specific sanction for the implantation of embryos already created with this technique: this gave the opportunity to multinational corporations operating in the area to provide those services even in Italy.

⁵ In Italy, a referendum held to repeal a law has to be voted by at least 50%+1 of citizens with the right to vote in order to be valid and reach its aim.

⁶ Percentage reached on the question aiming at abrogating the prohibition of fecundation with the intervention of a donor.

⁷ Percentage reached on the question aiming at abrogating the limit of the creation of three embryos.

⁸ Survey Unicab.

⁹ The latest referendum, held on 12 and 13 June 2011, represents an exception to this trend.

¹⁰ After recourse promoted by T.A.R. Lazio (Judgement 21 January 2008) and by Tribunal of Florence (Orders 12 July and 26 August 2008).

In particular, T.A.R. Lazio in its recourse invested Art. 14 Paragraphs 2 and 3 of the Law, underlining that requiring the creation of just three embryos, their implant in one attempt and prohibiting cryopreservation of them is in contrast with Art.3 and Art. 32 of the Constitution. The regulation drawn in Law 40 is felt to be irrational, since providing such restrictions contrasts with the very aim of the Law, which is to solve problems related to sterility or infertility. According to the T.A.R., the different interests of the woman and of the embryo were not balanced properly.

Similarly, the Tribunal of Florence raised the question of the constitutionality of Paragraph 2 of Article 14 of the Law finding it in contrast with Articles 3 and 32 of the Constitution. From a first perspective, the Tribunal

Article 14, Paragraph 2, established the limit of the creation of three embryos in the fecundation process and authorized only the possibility of a sole implant of such embryos. This provision was very strict, since a woman has to undertake very intense medical treatments in order to produce oocytes and the possibility of creating just three embryos greatly reduces the possibility of success, thus forcing her to go through such treatments several times. The Court declared such limitations not in conformity to the Constitutional provisions.

Article 14 Paragraph 3 basically prohibited cryopreservation of the embryos: the norm stated that cryopreservation of the embryos that could have been created during IVF was authorized only in case of severe and proven force majeure relating to the health of the woman and not predictable at the time of fecundation. But the Article stated also that the transfer should be completed in any case whenever possible, so the exception to the prohibition of cryopreservation was, however, only temporary, since the embryos were to be implanted anyhow, sooner or later. The Constitutional Court, with its ruling of 8 May 2009, n. 151 declared Paragraph 3 of Article 14 unconstitutional for not considering that the transfer of surplus embryos should be carried out without endangering the health of the woman. The Court balanced the protection of the embryo with the safeguarding of the woman, giving more freedom to the gynaecologist in the decisions on how many oocytes to fecundate and how many embryos to implant, with the presumption that he should act with “independence and responsibility” and, of course, in accordance with the informed consent of the patient¹². This judgement created an express contravention of the prohibition of cryopreservation.

However, even previously the consequences of the refusal of the woman to the implant had not been clear: there was no specific norm that provided for her criminal liability and, on the other hand, it clearly seems a violation to force her to have embryos implanted without her actual consent. The law is very brief and concise on this point, but further provisions can be found in the Guidelines of law 40/2004.

saw the health of the woman as prevalent in the balance with the embryo's health, thus echoing the well known Judgement of the Constitutional Court of 18 February 1975 n. 27 (on abortion).

In addition to that, the Court identified a violation of the principle of reasonableness in the provisions of the Law, seen as so separated from any concrete and specific need. Moreover the Tribunal underlined a violation of Art. 2 of the Constitutional Charter, since repeated treatments may lead to a violation of human dignity: such repetitions may be easily avoided by allowing the creation of more than three embryos and by authorizing cryopreservation. The Tribunal also found the Law unconstitutional in the light of Art. 3 of the Charter, for its not treating different situations differently. Finally, the Law was denounced also for its presumptive contrast with Art. 32 of the Constitution: forcing a woman to undertake severe medical treatments and to have infected embryos implanted may harm her physical and mental health.

¹¹ For being in contrast with Article 3 of the Constitution in relation to the principle of reasonableness and the principle of equality, since this provision was regulating different situations in the same way. The doctor could not consider the concrete case in order to minimize the risks, but had to comply with such a strict norm.

¹² This principle has already been stated in Judgements n. 338 of 2003 and n. 282 of 2002.

2.3. Guidelines: More than technical regulation

Indeed, the issue of cryopreservation is almost fully regulated by the Guidelines.

In fact, Article 7 of the Law states that the Minister of Health, in collaboration with the “Istituto Superiore di Sanità” and with the assent of the “Consiglio Superiore di Sanità” has to define procedures and techniques relating to IVF. Such guidelines become binding¹³ for all authorized institutions and have to be periodically updated, at least every three years, in conformity with technical and scientific progress.

Guidelines were issued on 21 July 2004 and were then updated on 11 April 2008¹⁴, with the express purpose of providing clear indications to the operators in order to ensure the full respect of the law. The 2008 update implemented the recommendations of the “Consiglio Superiore di Sanità”, firstly extending the possibility of using IVF also to people infected with sexually transmitted diseases. These individuals, who are not classified as “infertile¹⁵”, can benefit from such techniques¹⁶ and have children without any risk of infecting their partner or the baby¹⁷.

Secondly, new Guidelines ensured psychological support to women and couples undergoing assisted reproduction techniques along every step of the procedure, and also afterwards, in the case of failure. However, the need for psychological support was already recognized in most of the centers. Thirdly, claims for clarity in relation to pre-implantation diagnosis were heard and accepted: the Guidelines expressly state the impossibility of implementing prohibitions that are not already declared in the text of the law. The new version does not prohibit observational diagnosis, but merely forbids diagnosis for eugenic purposes¹⁸; this is in accord with pronouncements of the Judiciary that criticized such prohibitions included in the previous Guidelines, both ordinary and administrative,¹⁹ and, in particular, with the judgement of 21 January 2008, n. 398 of

¹³ The qualification of the Guidelines as a binding legal instrument is, indeed, in contrast with the very nature of Guidelines. As a matter of fact, usually such acts are just recommendations and suggestions compiled by experts and professionals, aimed at helping the doctor in approaching the concrete case of his patient. They differ from protocols, which, on the contrary, list a set of actions that must be carefully followed. The Italian Legislature clearly meant to provide a protocol, rather than suggestions, pursuing the idea of ensuring protection to the embryo.

¹⁴ The “Consiglio Superiore di Sanità” in its opinion of 19 July 2007 underlined the need for updating guidelines, due to scientific and technological developments. New Guidelines were signed by Minister Livia Turco and published in the *Gazzetta Ufficiale* on 30 April 2008, a few days after the establishment of the new Parliament. The “Consiglio Superiore di Sanità”, in its opinion of 9 April 2008 appreciated the conformity of the new text to its previous indications.

¹⁵ Such term was also the cause of a bitter debate, since up till 2004 the Legislature had chosen to consider infertility and sterility as synonyms.

¹⁶ Using special procedures like the intracytoplasmic sperm injection (ICSI, an IVF procedure that directly injects a single sperm into an egg) or the so-called “sperm washing”, a technique by which sperms are separated from seminal fluid.

¹⁷ However, even previously no sanctions had existed in the event of violation of such prohibition.

¹⁸ As already enshrined in Art. 13 of the law.

¹⁹ The case law on the issue of preimplantation diagnosis is very interesting: the first recourse was pending in May 2004 by different Associations of infertile couples (among which, the Hera Association) at The Tribunal of Catania. The Tribunal had to decide on a case that involved preimplantation diagnosis and the possibility of refusing the implant of an embryo with thalassemia. With the Ordinance of 3 May 2004 the Tribunal, in an *obiter dictum*, suggested the possibility of not proceeding with the implantation in case of physical and mental health risk to the health of the woman. The Constitutional Court rejected the recourse referring to the prohibition of embryo selection and to the prohibition of withdrawing consent to the implant, once expressed.

the T.A.R. Lazio, which annulled the part of the previous guidelines that limited embryo screening to a merely observational diagnosis²⁰. The morphological diagnosis on the embryo is based on mere microscopic observation, with no possibility of genetic screening: it is really though to monitor the health conditions of the embryo purely on the basis of this technique and, for the couple, it is almost impossible to be fully acknowledged²¹. Indeed, the 2004 Guidelines had introduced a prohibition *praeter legem* of all techniques of genetic diagnosis that had been widely applied in the past, in particular by couples with genetically transmittable diseases, like hemophilia, beta-thalassemia, cystic fibrosis, spinal muscular atrophy, sickle cell anemia, Duchenne and Becker muscular dystrophy. This provision was undoubtedly a cause of the increasing of the so-called “therapeutic tourism” towards countries with more liberal legislation. In addition, it created a paradoxical situation, if taken together with the provision of Law 22 May 1978, n. 194 entitled “norms on social protection of maternity and on abortion”, which is still in force and authorizes therapeutic abortion: a woman could not refuse the implant of an infected embryo but she could decide to have an abortion after the implant. Things improved in 2008. However, even with the changes brought about by the new Guidelines, the Legislature did not propose any express definition for the so-called “eugenic purpose”, thus leaving an evanescent situation of uncertainty.

The 2004 Guidelines in specifying Art. 13 of the Law, explicitly defines as “not coercible” the embryo transfer, stating that in event of the woman’s refusal of the implant,

A similar case was pending before Cagliari Tribunal in July 2005 (Ordinance of 16 July 2005): the applicants invoked Article 13 of the Constitution in an urgent action aimed at carrying out preimplantation diagnosis, refusing the transfer of embryos with thalassemia and cryopreserving them for a future implant. The Court declared with an Ordinance the inadmissibility of the question, since the question was not correctly presented. In May 2005 three proceedings were pending in front of the T.A.R. Lazio, promoted respectively by a couple, three medical centers and an association of medical centers, supported by several associations like Hera association, Cittadinanzattiva, Tribunale dei diritti del malato, Madre provetta, Amica cicogna. The actions aimed to bring an amendment to the restriction to the preimplantation diagnosis introduced by the Guidelines and not presented in the law. T.A.R. rejected all three recourses.

Things started to change in September 2007, with a recourse pending in front of the Cagliari Tribunal. The applicants asked to be authorized to carry out preimplantation diagnosis. The court, with its judgment of 22 September 2007, upheld the appeal allowing the couple to undertake this exam, basing its decision on a constitutionally orientated interpretation of the norm, according to Art. 3 and 32 of the Constitution: the couple has the right to be fully informed of the health status of the embryo and the woman cannot be forced to complete the transfer. After this judgment, also the Tribunal of Florence in an Ordinance of 17 December 2007 upheld the recourse of a couple, authorizing the preimplantation diagnosis and authorizing not to transfer the embryo affected by multiple exostoses. The judge stated that prohibition of preimplantation diagnosis and of cryopreservation of the embryos must be derogated in order to ensure the safeguard of the woman’s health, in conformity with the best scientific practice. Moreover, such techniques may be applied only under specific conditions: it must be requested by the couple itself, it must be related only to the embryos that are about to be implanted, it must aim at screening any disease without any regard for other genetic characteristics and it must be finalized to provide adequate information about the health of the embryos.

²⁰ The recourse was presented by W.A.R.M., World Association Reproductive Medicine and opposed by “Forum delle Associazioni Familiari” (forum of family associations), “Federazione Nazionale dei Centri e Movimenti per la vita” (national federation of pro-life centers and movements) and “Comitato per la tutela della salute della donna” (committee for the protection of the health of the woman), which all intervened in the proceeding.

²¹ In this perspective, the preimplantation diagnosis is seen as a form of eugenic selection, thus affecting the dignity of the embryo. The rights of the couple to be informed and to decide are secondary: the embryo is recognized as a subject that holds rights (Art.1 of Law 40/2004).

the *in vitro* culture must be maintained until its extinction. With the above-mentioned ruling of T.A.R. Lazio, 21 January 2008, n. 398, such provision has been annulled.

In relation to Art. 14 of the Law, the Guidelines explicitly repeat that the embryo can be cryopreserved in the particular situation described in the law and, on that point, add that every embryo which is not implanted has to be cryopreserved at the expense of the IVF centre while pending the future implant.

In order to fulfil this purpose, all the medically assisted procreation centres that adopt IVF techniques must be well equipped with the appropriate tools for cryopreserving and thawing embryos. Embryos must be preserved in dedicated cryogenic containers, while the rooms dedicated to cryopreservation of gametes and embryos must have adequate structural and security features and must only be used to carry out that specific activity. Moreover, regarding breakages or malfunctioning of cryogenic containers and storage systems, all centers must implement the appropriate security measures. Guidelines are very precise also on security measures: they state that the operating procedures for each phase of use of paillettes and test tubes must be written down, in order to minimize the risk of contamination and the loss of samples of cryopreserved materials²².

Still in relation to laboratory and security structures, the Guidelines regulate access to the conservation area²³ and to the system of locating embryos²⁴. At the end of the section, the Guidelines request the creation of a monitoring system of the whole institution in order to ensure high safety standards during the delicate procedures of manipulation and conservation of both gametes and embryos. In addition to that, security must be ensured also from another perspective: a system of monitoring errors, non-conformity and adverse events occurring to people using assisted fertilization services must be created.

The Law does not expressly regulate identification procedures, but the Guidelines are very strict on this point: the names of the individuals from whom the gametes were taken, or from whom embryos were generated, must be carefully registered and samples must be labeled in order not to permit unauthorized or unrecognizable alterations. Moreover, a proper registration system must be enforced in order to permit the traceability of each step of the processing of oocytes, of samples of seminal fluid and of embryos. And, of course, all these steps should be carried out by operators authorized from the original date of collection.

The Guidelines also provide a complete set of rules for monitoring cryopreservation, establishing yearly inspections. These regulations are intended for checking that the data recorded on the forms corresponds to the genetic material actually stored, for

²²The list of written procedures is very detailed. The Guidelines request written procedures also in relation to cleaning, maintaining and filling of cryogenic containers, monitoring access to such containers, freezing and thawing of embryos, the location of samples and the duration of storage, transport of contaminated samples, but request written procedures also in relation to staff qualification.

²³ The access to the gametes and embryos storage area should be allowed only to authorized personnel, that is to say, those capable of performing the related activities, while no other person should have access to such area.

²⁴ In order to save time during the operations of insertion and extraction of cryogenic containers, the exact localization of gametes and embryos must be accurately recorded. The norm is more demanding: it requests that each stage of gametes and embryos manipulation must be recorded.

verifying purposes and duration of cryopreservation and for any other action deemed necessary. In addition to that, the Guidelines provide specific regulation of documentation related to the gametes and the embryos²⁵. Other provisions deal with the issue of checking cryopreservation: the scientists must collect documentation relating to thawing oocytes and embryos and such documentation shall include any morphological change observed both during thawing and during the culture.

A leading role is played by the individuals who own gametes and embryos: as a matter of fact, according to the Guidelines, they have to be informed when the conservation period is about to expire, in order to be properly prepared for choosing among all the possible options. Moreover, they must be contacted if the storage centre is closing down or if its authorization has not been renewed or if the region has decided to withdraw it. The different options are also linked to the different embryo conditions. Indeed, two embryo categories can be drawn: embryos that are about to be implanted, including embryos cryopreserved before the entry into force of Law n. 40/2004, and embryos in declared status of abandonment²⁶. The norms relating to this second category show the limits of Art. 14 of the Law, since they are concrete proof of the impossibility of implementing the prohibition of cryopreservation. The condition of state of abandonment of an embryo is realized when the two parents or the single woman²⁷ have signed a written waiver to future implant or when, after a year of attempts to contact the couple (or the woman), there is a documented inability to trace the couple (or the mother). The abandoned embryos will be cryopreserved in a centralized institution, financed by the State, while the woman maintains the right to claim and obtain the implant of the cryopreserved embryos²⁸.

The regulations detailed in the text also pay attention to the health of the embryo itself: a section of the Guidelines, entitled “Contamination”, focuses on the risk of infections and tries to prevent them²⁹. Moreover, the Guidelines fix the procedure to be

²⁵ Such records are very precise and must include: type and number of the used cryoprotectant, the stage of embryonic development, the number of embryos contained in each paillette, the number of oocytes contained in each paillette, the concentration of motile sperm contained in each sequins and the number of paillettes preserved for each patient.

²⁶ But, in any case, the costs for freezing will be sustained by the centre for medically assisted procreation. This will be different for cryopreservation.

²⁷ Before Law 40/2004, in the case of embryos produced with the sperm of a donor and in the absence of a male partner.

²⁸ Also in this case the costs of cryopreservation are borne by the State.

²⁹ The norm states that the cryopreserved gametes and embryos must be kept away from any radioactive material and from any other, even potential, source of infection or atmospheric and chemical contamination. Besides this, people that are benefiting from the services offered in assisted fertilization programs must undertake tests for hepatitis B, hepatitis C and HIV, with the guarantee of the application of all the adequate privacy measures in relation to the results. The Guidelines are even more specific, establishing that the samples must be kept in different containers depending on the outcome of the tests: samples from individuals who resulted negative for hepatitis B, hepatitis C and HIV have to be stored in different cryogenic containers from samples which tested positive or which are just lacking a proper documentation of negativity. And, in particular, even such samples must be separated from every sample resulting positive, which has to be stored in a container specific for its disease. Therefore the centre must be equipped with multiple types of containers: for negative samples, for pending-report samples and for positive samples, divided by the various infectious diseases (hepatitis B, hepatitis C or HIV).

followed to verify that the necessary requisites exist to be eligible for the techniques³⁰ and, more precisely, require a screening for infectious diseases³¹.

For each couple a detailed medical record must be filed³², together with an individual laboratory sheet³³ and such documents have to be conserved in the centre. A final report³⁴ is given to the couple and then delivered to the doctor.

In the end, the possibility of transferring gametes and embryos to another centre is subject to guarantees and safety measures, described both in general³⁵ and more particularly in relation to consent³⁶.

3. Fundamental Rights Involved and Emerging Difficulties

Balancing the rights of the embryos with the rights of the woman and, more in general, of the couple is a very delicate issue. This complex situation involves fundamental rights, technical aspects and normative difficulties.

As regards fundamental rights, guaranteed both at international and at Constitutional level, many different issues are involved.

Firstly, the right to life is emerging with a new and strong meaning: even the embryo can be seen as a holder of such a right (this was the point of view held by the lawyers of Natallie Evans³⁷). Secondly, the right to have a family can be perceived in a

³⁰ People who are going to undertake treatments in a centre for medically assisted procreation must carry out the tests listed in D.M. 10 September 1998.

³¹ Human Immunodeficiency Virus (HIV), hepatitis B (HBV) and hepatitis C (HCV) screening. In the event of infection, the couple and the medical centre have to consider carefully the potential implications of such diseases for children.

³² Such medical record must register the identities of both partners, their contact details and their anamnesis, any examination they have undergone, the diagnosis, the selected treatment, the complete description of the procedures carried out, but also any anesthetic, sedative, analgesic technique applied, the names of the operator, the clinical developments, any complication which occurred and the outcome of the treatment.

³³ Whose content is very meaningful: it must include records of every aspect of the procedure. Guidelines request a description of the seminal fluid characteristics both before and after preparation, the number of oocytes and their degree of maturity, and the method used for preparing samples, the number of oocytes inseminated, the number of fertilized eggs, the number of embryos and their morphological description, the number of the transferred embryos, every stage of embryonic development. And, of course, a record must be kept gathering the number of cryopreserved oocytes, the number, if existing, of cryopreserved embryos, and the encoding used to identify oocytes and embryos.

³⁴ It must contain information about the procedures used, with all the technical details, the data of the endocrine and ultrasound monitoring, all the other data collected in the laboratory, the medications used (if any) during collection, the final situation and any other therapeutic indication useful for the period following the procedure.

³⁵ Guidelines just state that, while transferring gametes and embryos to a different centre, the personnel have to observe procedures for preserving the quality and safety of such materials. Another quite declaratory provision urges the centers of storage, treatment and research to ensure the smooth and correct transfer of gametes and embryos.

³⁶ The receiving centre has to verify the subsistence of the consent of individuals from whom gametes and embryos have been created in relation to any kind of use and storage of such gametes and embryos.

³⁷ The case (*Evans v. the United Kingdom*, Grand Chamber of the European Court of Human Rights, 10 April 2007) involved a couple of British citizens who contacted a specialized center for medically assisted reproduction. The woman had cancer and, before stating the pregnancy, she had to undergo an operation to have her ovaries removed. Before starting the cancer treatment, the couple created an embryo through IVF,

deeper way, which comprises a concrete expectation of growing a baby once the embryo is created. This argument is particularly controversial in situations of conflicting wills between the parents before the implant, premature death of one parent, or separations. Thirdly, everything has to be balanced respecting the basic principle of equality between genders. The different implications of the implantation of the embryo for the woman may lead to different weight being given to the consent or refusal of the two partners.

In addition to this, there is uncertainty also in relation to technical aspects, mainly due to the essential difficulty of carrying out research on this theme.

In particular, there is no scientific parameter commonly shared regarding the time limit of cryopreservation of the embryos³⁸; moreover, experimentation aimed only at discovering the consequences of the implant of an “expired” embryo would be, without any doubt, ethically unacceptable.

Another technical difficulty regards a different issue: Italian Law expressly allows the conservation of the gametes (Art. 14 Paragraph 8 of Law 19 February 2004, n. 40) but the techniques involved in this field are still on an experimental level.

Moreover, there is the problem of the existing embryos that were cryopreserved before the entry into force of Law 19 February 2004, n. 40 and, after the judgment of the Constitutional Court, of the embryos that are created but not implanted to safeguard the health of the woman. Those embryos cannot be used for scientific research, cannot be destroyed and cannot be donated to other infertile couples and their number is constantly increasing: according to the “Istituto Superiore di Sanità”, in Italy there are 3.415 cryopreserved and abandoned embryos from 825 couples and 6.079 embryos whose parents are unknown³⁹. Practical problems involve also the resources and the costs of such conservation. In Italy there are 200 specialized centres, which are currently financed and paid for cryopreserving the embryos indefinitely for no concrete purpose⁴⁰.

In the end, as regards normative difficulties, there is a fine line to be drawn between legal and illegal in this field and to define the value and the power of informed

with the purpose of implanting it in the uterus of the woman after her recovery. But, by the time of her recovery, the couple had already split up. The man withdrew his consent to the implant of embryos on the basis of the Human Fertilization and Embryology Act of 1990: the UK legislation authorizes both parents to refuse the implant till the very moment of the implant. The woman, after unsuccessfully recourse to UK domestic courts, appealed to the European Court of Human Rights. She catalogued the possibility offered by the HFEA as a violation of her right to have a baby, defining such option as a violation of Art. 2 (right to life, in relation to the embryo to come to life), Art. 8 (right to respect for private and family life), Art. 14 (prohibition of discrimination) of the ECHR. The Court, with the judgment of 10 April 2007, declared that there was no violation of such right. This difficult balance involves the rights of man and of woman, but also the importance of consent and legal certainty, touching both individual and collective interests: the UK law protects human dignity and free will and such rights are compatible with the ECHR.

³⁸ As a matter of fact, some legislation fixed the time limit at 5 years, others at 10, while the Italian law allows for cryopreservation for good.

³⁹ Data provided by the Istituto Superiore di Sanità and communicated by Professor Anthony Wilhelm, Director of Unity of Reproductive Medicine of Hera, on 27 January 2011, during the legal and scientific seminary entitled “Destiny of abandoned embryos: a new parenting possibility”, held within the National Parenting Week organized by the HERA Foundation. (Online, URL: <http://salute24.ilsole24ore.com/articles/12588-salute-in-italia-oltre-6mila-embrioni-orfani?refresh_ce>; last visit 30/05/2011).

⁴⁰ In Italy there are also 15 public banks for preserving umbilical cord.

consent: even in an area that shares the same values, Europe, the national Legislatures have chosen different solutions.

As a first overview and as a general example, in Denmark, France, Greece, The Netherlands and in Switzerland, consent can be revoked until the time of implant, while in Austria and Estonia it is revocable only up until fertilization: every subsequent decision is up to the woman. In Germany and in Italy (two of the three countries that are also blocking the adoption of the European Commission's Anti-discrimination Directive), consent cannot be revoked.

4. The European Context: Different Perspectives

Looking in greater depth into the analysis of the different regulations, it immediately appears clear that almost every single State in the European area has chosen different solutions for such a delicate issue. This situation leads to a so-called "therapeutic tourism" within Europe. For instance Spain, with its liberal legislation, is the favourite destination for people who want to donate eggs, while Italy and Germany are very restrictive countries, from which people tend to leave. The criteria for choosing a foreign country are related to the possibility of performing pre-implant diagnosis, of creating embryos without heavy numerical restrictions, and of overcoming numerical limitations in the implant.

In particular, in Austria it is possible to select oocytes before the implant: fecundation is carried out only on the embryos that will be implanted. Cryopreservation for a future implant is admitted, with a time limit of one year, after which the embryos are disrupted.

Denmark has very liberal legislation: cryopreservation of oocytes is legal for two years: after this period of time, oocytes must be disrupted. Also cryopreservation of embryos, preimplantation diagnosis and gender selection (but only to avoid sex-related diseases) are legal. As regards research, this can be carried out solely for diagnosis preimplantation and on surplus embryos, of maximum 14 days old, and they can be cryopreserved for at least two years. After experimentation, embryos can be implanted only if they have not been damaged during the trials.

France has recently changed its bioethics law⁴¹: before 2004 all experimentation on embryos was banned (except for trials carried out purely for the health of the embryo itself and within 7 days). The new Law (800/2004) authorizes research on the embryo and stem cells for 5 years, as for cryopreservation.

Germany adopts very restrictive regulation, which prohibits fecundation and development of embryos for any purpose different from pregnancy and prohibits research on the embryos (which can, however, be authorized purely for the health of the embryos themselves).

On the other hand, Great Britain, in its Acts of 1990 and 2001, follows a very different approach. The legislation in place does not fix a numerical limit for the produc-

⁴¹ After law n. 94-653, n. 94-654, n. 94-548 the "Code de la santé publique" (law 800/2004) was issued.

tion of embryos: usually between 12 and 14 embryos are created, then the best are selected for the implant, with a limit to the implant related to the age of the woman (2 embryos if the woman is under 40 years, 3 if she is over forty). The woman is not obliged to have the embryos implanted and cryopreservation is legal. Moreover, research on the embryos is permitted (till day 14), but only for authorized projects.

Portugal presents a peculiarity, since assisted reproductive technology is cited directly in the Constitution. Article 67 states that, in order to safeguard human dignity and to protect the family, assisted reproductive technology must be regulated. Moreover, in this country cryopreservation is permitted and the gynaecologist can decide autonomously how many oocytes fecundate.

Spain has a very elastic legislation too, since in this country fecundation with the gametes from a donor, cryopreservation of embryos, experimentation on non-vital embryos and pre-implant diagnosis are legal. The woman can revoke her consent till the time of implant and surplus embryos can be used for other implants, or donated to other infertile couples or to research or to be cryopreserved. Moreover, scientific research is very much encouraged in Spain: the only prohibition is related to the creation of embryos purely for research, but research is legal, with differences, on already existing pre-embryo/embryo/foetus⁴². As regards research on the embryos, this has to be subject to strict principles, and to be carried out solely for therapeutic aims, with the written consent of parents, on embryos of maximum 14 days old. Research on pre-embryos is prohibited if a similar result can be obtained by investigating on animals.

In Sweden too, cryopreservation of embryos is legal, if authorized (for a maximum limit of 5 years). The possibility of pre-implant diagnosis and research on embryos are also legal. In particular, experimentation has to be undertaken within the first 14 days of life of the embryo, with the consent of the parents and must not genetically modify the embryo. After the trial, the embryo has to be disrupted.

⁴² This is a peculiar classification offered by Law of 26 May 2006, n. 14, on medically assisted reproduction.

5. Conclusion

After this brief overview, it is evident that the Italian position is very restrictive even in a European perspective. Presumably, religious pressures may have influenced the Legislature⁴³, since, in regulating this topic, the law is a meaningful collection of principles, but is too detached from the European context⁴⁴. Another critical point of the current regulations are the antinomies with the law on abortion, previously analysed, and the discriminatory effect which is being created between couples that can afford to go abroad to undertake treatment and other couples.

In this context, in Italy, the activity of the Courts seems to be filling the regulatory voids left by the Legislature, which has had the difficult task of dealing with these delicate issues and of balancing different fundamental values for the first time. Law 40 has to face another challenge: recourse is pending before the Constitutional Court in relation to fecundation from a donor⁴⁵.

⁴³ And also in the days before the referendum for repealing Law 40/2004, the Catholic Church strongly opposed the vote.

⁴⁴ Italy is in the same situation in relation to civil union.

⁴⁵ Case of S.H. and others v. Austria, Application no. 57813/00: two Austrian couples with fertility problems, which could have been overcome only through in vitro fertilization with eggs or seminal fluid from a donor, could not approach such techniques since the Austrian law does not authorize them. Also the Austrian Constitutional Court refused to annul the legislative provision and stated that the regulation was in conformity with the European Convention.

The Court of Human Rights, in its judgment of 10 April 2010 extended the protection of Article 8 (on private and family life), even to people willing to become parents, in order not to discriminate (Article 14 of ECHR) between people in similar situations.

After this important judgment, also in Italy similar recourses are being undertaken: the first one was in front of the Tribunal of Bologna on 6 May 2010 and, up to now, there are other recourses pending before the Tribunals of Catania, Florence, Genova, Rome, Milan, Naples.

References

- Bernasconi C. (2009). *Cellule staminali e medicina rigenerativa 2009: attualità e prospettive*, (Collegio Ghislieri, Pavia, 16-20 marzo 2009). Edizioni internazionali srl divisione EDIMES, Pavia.
- Bompiani A., A. Loreti Beghè, L. Marini (2001). *Bioetica e diritti dell'uomo nella prospettiva del diritto internazionale e comunitario*. Giappichelli, Torino.
- Boschiero N. (2006). *Bioetica e biotecnologie nel diritto internazionale e comunitario – Questioni generali e tutela della proprietà intellettuale*. Giappichelli, Torino.
- Braude P., S. Muhammed (2003). “Abc of Subfertility: Assisted Conception and the Law in the United Kingdom”. *British Medical Journal*, 327(7421).
- Camassa E., C. Casonato (2006). *La procreazione medicalmente assistita: ombre e luci*. Giappichelli, Torino.
- Casonato C. (2007). *Life, technology and law*. CEDAM, Padova.
- Casonato C., T. E. Frosini (2006). *La fecondazione assistita nel diritto comparato*. Giappichelli, Torino.
- Fineschi V., M. Neri, E. Turillazzi (2005). “The New Italian Law on Assisted Reproduction Technology (Law 40/2004)”. *Journal of Medical Ethics*, 31(9).
- Fusco M. (8 April 2006). “Procreazione assistita, i genitori possono revocare il consenso. La legge britannica va d'accordo con i diritti dell'Uomo”. *Diritto e giustizi@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegiustizia.it>>.
- Fusco M. (24 June 2006). “Il futuro della medicina tra speranze e (molti) veti”. *Diritto e giustizi@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegiustizia.it>>.
- Fusco M. (29 January 2008). “Diagnosi preimpianto: oggi si può? La situazione dopo il cambio di rotta del Tar Lazio”. *Diritto e giustizi@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegiustizia.it>>.
- Fusco M. (10 May 2008). “Nuove linee guida sulla procreazione assistita: canto del cigno o reale cambiamento?”. *Diritto e giustizi@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegiustizia.it>>.
- Fusco M. (12 May 2009). “La scure della Consulta sulle illegittimità della Legge 40”. *Diritto e giustizi@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegiustizia.it>>.
- Mandelbaum J. (2000). “Embryo and oocyte cryopreservation”. *Human Reproduction*, 15(4).
- Munn D., L.M. Guenin (2001). “Moral Issues of Human Embryo Research”. *Science New Series*, 293(5528).
- Pennings G. (2005). “Legal Harmonization and Reproductive Tourism in Europe”. *Reproductive Health Matters*, 13(25).
- Robertson J.A. (1990). “In the Beginning: The Legal Status of Early Embryos”. *Virginia Law Review*, 76(3).
- Santosuosso A., S. Garagna, B. Bottalico, C.A. Redi (2010). *Le scienze biomediche e il diritto – Biomedical sciences and the law*. Ibis, Como-Pavia.

- Santosuosso A., G. Gennari, S. Garagna, M. Zuccotti, C.A. Redi (2004). *Science, Law and the Courts in Europe*. Ibis, Como-Pavia.
- Sieck W.A. (1998). “In Vitro Fertilization and the Right to Procreate: The Right to No”. *University of Pennsylvania Law Review*, 147(2).
- Stanzione P., G. Sciancalepore (2004). *Procreazione assistita – Commento alla legge 19 febbraio 2004, n. 40*. Giuffrè, Milano.
- Stefanini E. (2008). *Dati genetici e diritti fondamentali – Profili di diritto comparato ed europeo*. Cedam, Padova.
- Tavola rotonda: Argomenti etici (e politici) nella ricerca sulle cellule staminali*, (Aula Magna del Collegio Ghislieri Pavia, 16 febbraio 2007). Edizioni internazionali srl divisione EDIMES, Pavia.
- Veronesi P. (10 September 2005). “Diagnosi preimpianto: i nodi al pettine della Consulta, il tribunale di Cagliari evidenzia le contraddizioni”. *Diritto e giustizia@, il quotidiano di informazione giuridica*. [Online], available at: <<http://www.dirittoegustizia.it>>.
- A, b, et c c. Irkande (Novembre 2010 – février 2011). *Bulletin d'information sur les droits de l'Homme*, 8.

Websites

- Belotti F., “La fecondazione eterologa a Strasburgo”.
URL: <<http://www.dirittoweb.org/diritto-comparato/20-la-fecondazione-eterologa-a-strasburgo.html>>.
- Casonato C., “Legge 40 e principio di non contraddizione. Una valutazione d’impatto normativo della disciplina sulla PMA”.
URL: <http://webcache.googleusercontent.com/search?q=cache:ye-2gZpscc8J:www.jus.unitn.it/dsg/ricerche/bidiritto/docs/casonat_pma.rtf+donna+embrioni+revoca+consenso+impianto+svizzera+danimarca+italia&cd=1&hl=it&ct=clnk&gl=it&client=firefox-a&source=www.google.it>.
- Costantini M.P., “Nota a prima lettura di Sentenza della Terza Sezione del TAR Lazio 21 gennaio 2008 n. 398”. URL:
<<http://www.federalismi.it/ApplMostraDoc.cfm?Artid=9166&edoc=07042008183908.pdf&tit=Nota%20a%20prima%20lettura%20TAR%20Lazio,%20Sent.%20n.%20398/2008,%20in%20materia%20di%20procreazione%20medicalmente%20assistita>>.
- Mandelbaum J., J. Belaïsch-Allart, A.-M. Junca, J.-M. Antoine, M. Plachot, S. Alvarez, M.-O. Alnot, J. Salat-Baroux, “Cryopreservation in human assisted reproduction is now routine for embryos but remains a research procedure for oocytes”. URL:
<http://humrep.oxfordjournals.org/content/13/suppl_3/161.full.pdf+html>.
- Pimentel G.J. “Evans v. United Kingdom, to procreate or not to procreate: which right is greater?”. URL:
<http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=gabe_pimente1_pimentel&seiredir=1#search=%22embryo+revoked+consent+implant+italy+switzerland+england%22>.

Razeto G. (ed.), *Notizie di Bioetica, Biopolitica, Biodiritto*.

URL: <<http://notiziedibioetica.blogspot.com>>.

“Il diritto alla vita del bambino concepito - dalla negazione alla promozione del diritto alla vita”, URL:

<<http://www.centrodirittiumani.unipd.it/scuola0304/terzo/vicenza/dirittoallavita.pdf>>

<<http://bioetiche.blogspot.com/2006/03/sul-caso-di-natalie-evans.html>>

<http://club.quotidiano.net/q/embrioni_congelati_quale_destino>

<<http://salute.aduc.it/staminali/normativa/>>

<<https://wcd.coe.int/wcd/ViewDoc.jsp?id=61325>>

<<http://www.inail.it/repository/ContentManagement/information/P1455022747/XQ0P9.pdf>>

<<http://www.evidenze.com/cellule-staminali/legislazione-italiana/>>.

<<http://www.ivf-infertility.com/ivf/standard/regulations.php>>.

<<http://www.lucacoscioni.it/rassegnastampa/embrioni-crioconservati-verso-un-decreto-ministeriale>>

<http://www.lucacoscioni.it/search/apachesolr_search/crioconservazione>.

Abstract

Law&Science Young Scholars Informal Symposium – 2011 Round

A cura di Chiara Boscarato – Franco Caroleo – Amedeo Santosuosso

L'evento "Law&Science Young Scholars *Informal Symposium – 2011 Round*" è stato realizzato su iniziativa del Centro di Ricerca Interdipartimentale "European Centre for Law, Science and New Technologies" (ECLT) dell'Università di Pavia in collaborazione con il Collegio Ghislieri, l'Istituto Universitario di Studi Superiori (IUSS) di Pavia e la Fondazione Maugeri di Pavia.

Il Simposio prevede la partecipazione di giovani ricercatori nel settore Diritto&Scienza. Una Commissione internazionale di esperti in materie giuridiche e scientifiche seleziona i partecipanti, fornendo anche a ciascun candidato considerazioni sui punti forti e consigli per migliorare i punti deboli del proprio contributo. L'intento è quello di creare un evento interamente dedicato ai giovani, in cui presentare i risultati delle proprie ricerche, conoscere e confrontarsi con altri giovani studiosi attivi nello stesso campo e ricevere un prezioso feedback sul proprio lavoro.

La giornata è aperta al pubblico e le due sessioni sono usualmente introdotte da una *Keynote Lecture* tenuta da un esperto internazionale. Nel 2011 il Simposio ha ospitato John Searle, uno dei maggiori filosofi viventi, e Orsetta Zuffardi, docente di Genetica Medica dell'Università di Pavia. Per l'anno 2011 è stato istituito il "Fondazione Maugeri 2011 Law&Science Young Scholar Prize", un premio in denaro offerto dalla Fondazione "Salvatore Maugeri" ai due migliori elaborati, mentre il terzo classificato ha avuto una menzione speciale.

I contributi riguardano il particolare settore dell'interazione tra diritto, scienza e nuove tecnologie, in particolare neuroscienze, biobanche, test genetici e biologia sintetica. L'uso della lingua inglese e la selezione dei partecipanti tramite un processo di revisione in più fasi, svolto da un gruppo di esperti provenienti da tutto il mondo, assicurano la qualità scientifica dei contributi raccolti.

Per maggiori informazioni si può visitare la pagina web dedicata all'evento sul sito del centro ECLT: <<http://www.unipv-lawtech.eu>>.

Chiara Boscarato e Franco Caroleo sono dottorandi di ricerca presso il Dipartimento di Diritto Privato, Diritto Romano e Cultura Giuridica Europea della Facoltà di Giurisprudenza dell'Università di Pavia. La loro attività di ricerca è svolta in collaborazione con il Centro ECLT.

Amedeo Santosuosso, docente del corso "Law, Science and New Technologies" presso l'Università di Pavia, è tra i fondatori e il Presidente del Centro ECLT.