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Articles

Enrique Santamaría*

Contracts on Human Biological Samples: the European Prohibition of Financial Gain from the Human Body and its Parts

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Abstract: Several European law documents (including the Charter of Fundamental Rights of the European Union) lay down a general prohibition on making the human body and its parts, as such, a source of financial gain. Scholars have identified three reasons for this prohibition: human dignity, equality, and solidarity. This paper aims at exploring to what extent non-gratuitous contracts on human biological samples can be validly concluded for purposes of research and commercial applications of the research results. In particular, the present paper will firstly, analyse the role of the three aforementioned reasons – dignity, equality, and solidarity – in the assessment of the validity of non-gratuitous contracts on human biological samples for the purposes of research and possible commercial uses thereof. Secondly, this paper will outline some possible advantages of excluding this kind of contracts from the scope of application of the prohibition of financial gain.

Resumé: De nombreux documents de droit européen (y compris la Charte des droits fondamentaux de l'Union européenne) prévoient une interdiction générale de faire du corps humain et de ses parties, en tant que tels, une source de profit. Les chercheurs ont identifié trois raisons à cette interdiction: la dignité humaine, l'égalité et la solidarité. Cet article vise à déterminer dans quelle mesure des contrats à titre onéreux sur des échantillons biologiques humains peuvent être valablement conclus à des fins de recherche et applications commerciales des résultats de la recherche. En premier lieu, le présent document analyse le rôle des trois raisons susmentionnées: la dignité, l'égalité et la solidarité dans l'évaluation de la validité des contrats à titre onéreux sur des échantillons biologiques humains aux fins de recherche et les possibles utilisations commerciales des résultats de la recherche. En second lieu, cet article

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expose certains avantages possibles de l'exclusion de ce genre de contrats du champ d'application de l'interdiction de faire du corps humain et de ses parties une source de profit.

Zusammenfassung: Verschiedene EU-Dokumente (einschließlich der EU-Grundrechtecharta) schreiben fest, dass der menschliche Körper nicht als Quelle finanzieller Gewinne genutzt (missbraucht) werden darf. In den Rechtswissenschaften werden drei Rechtfertigungen für dieses Verbot vorgebracht: die Menschenwürde, der Gleichheitssatz und das Solidaritätsprinzip. Ziel dieses Beitrages ist es zu eruieren, inwieweit Verträge ohne finanzielle Gegenleistung über menschliche biologische Proben wirksam abgeschlossen werden können, um Wissenschaft zu betreiben und die so gefundenen Erkenntnisse dann auch kommerziell zu verwenden. In diesem Kontext werden zwei Hauptargumentationslinien entwickelt: Zunächst werden die genannten Grundsätze (Menschenwürde, Gleichheitssatz und Solidaritätsprinzip) fruchtbar gemacht für eine Bewertung der genannten Verträge ohne finanzielle Gegenleistung. Sodann wird versucht zu begründen, welche Vorteile es hätte, wenn diese Art Verträge gänzlich aus dem Anwendungsbereich des Verbotes ausgenommen würden.

I Introduction

Human body parts may be used for various purposes: therapeutic purposes (eg organ and tissue transplants), research on human biological samples for academic or commercial purposes (eg the development of medicines), museum collections, exhibitions of cadaveric parts, etc. The present paper will only consider one of these purposes: research on human biological samples and possible commercial uses of this research. For the purposes of this paper, the term human biological sample should be understood as a part of the human body, separated from it, that contains the genetic makeup of an individual.¹ Human organs are not included in this definition.

Due to the development of new technologies in genetic research and the increasing understanding of the human genome,² human biological samples have

¹ On this definition see P. Nicolás Jiménez, 'Los derechos del paciente sobre su muestra biológica: distintas opiniones jurisprudenciales' (2003) 19 *Revista de Derecho y Genoma Humano* 208.

² See for example the Human Genome Project (HGP), aimed at mapping human DNA. For information on the Human Genome Project see <https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/>.

become the object of different kinds of applications in the fields of research, diagnosis and medical treatment. In fact, human biological samples constitute a precious source of (genetic) information for researchers looking to develop new treatments, diagnosis methods (eg genetic tests) or products to be sold on the market (eg medicines). The use of human biological samples raises an innumerable amount of (bio)ethical and legal issues, ranging from the requirements for the validity of the consent of the transferor of the samples, to the protection of the fundamental rights of the transferor of the sample.

This paper deals with one specific legal and ethical question: To what extent can non-gratuitous contracts on human biological samples be validly concluded for purposes of research or commercial applications of research results?

Several European law documents on fundamental and human rights include a prohibition on making the human body and its parts, as such, a source of financial gain (hereafter: prohibition of financial gain). This is the case, for example, of Article 21 of the Council of Europe Convention on Human Rights and Biomedicine³ (hereafter: Oviedo Convention) according to which the human body and its parts shall not, as such, give rise to financial gain⁴ and Article 3 subparagraph 2 literal c of the Charter of Fundamental Rights of the European Union⁵ (hereafter: CFREU), on the prohibition on making the human body and its parts as such a source of financial gain.⁶

The scope of application of the prohibition of financial gain embodied in the aforementioned documents has an undeniably general character. It does not distinguish between different body parts (eg organs, tissues, bodily fluids, cells), and does not differentiate between the intended uses of these parts.

Other European norms include prohibitions similar to the ones of Article 21 of the Oviedo Convention and Article 3 CFREU, but they do distinguish between different body parts or intended uses thereof. For example, Recital 23 of the

3 Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Right and Biomedicine, adopted in Oviedo, Spain, on 4 April 1997. CETS No 164.

4 Art 21, entitled 'Prohibition of financial gain', reads: 'The human body and its parts shall not, as such, give rise to financial gain'.

5 Charter of Fundamental Rights of the European Union (2012/C 326/02) Published in the Official Journal of the European Union C 326/391 26 October 2012. The Charter of Fundamental Rights of the European Union was proclaimed 7 December 2000, and entered into force 1 December 2009 with the Treaty of Lisbon.

6 Art 3(2) reads: 'In the fields of medicine and biology, the following must be respected in particular: (...) c. the prohibition on making the human body and its parts as such a source of financial gain.'

European Blood and Blood Components Directive 2002/98/EC⁷ encourages voluntary and unpaid donations of blood and blood components.⁸ Moreover, Article 12, subparagraph 1 of the European Tissue and Cells Directive 2004⁹ prescribes that Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.¹⁰ Finally, Article 6 of the Appendix of the Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological materials of human origin¹¹ states that biological materials of human origin should not, as such, give rise to financial gain.¹²

All the above mentioned provisions arguably constitute a system, from which a general prohibition of financial gain from the human body and its parts has been distilled.¹³

Should the general prohibition of financial gain be applicable to all non-gratuitous contracts on human body parts? Or can perhaps a non-gratuitous contract between the first transferor and the first transferee of a human biological sample be validly concluded, under certain circumstances?

II Scope of this paper

There is abundant literature on the subject of commodification of the human body and its parts, and particularly on the issues of markets on human organs,

7 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC *OJ L33/30*.

8 Recital 23 reads: '(...) (A)ll necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account'.

9 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] *OJ EC L102/48*

10 Art 12(1) reads: 'Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells'.

11 Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological materials of human origin (Adopted by the Committee of Ministers 11 May 2016 at the 1256th meeting of the Ministers' Deputies).

12 Art 6 reads: 'Biological materials of human origin should not, as such, give rise to financial gain'.

13 See for example G. Resta, 'La disposizione del corpo. Regole di appartenenza e di circolazione', in S. Rodotà / P. Zatti (a cura di), *Trattato di Biodiritto, Il governo del corpo* (Milano: Giuffrè Editore, 2011) 814.

surrogacy, genetic therapy and enhancement.¹⁴ However, the literature on the validity of non-gratuitous contracts on human biological samples is scarce.¹⁵ This paper intends to contribute to filling this gap in legal science.

The prohibition of financial gain from the human body and its parts seems to rest on three main legal and ethical considerations:

The first consideration is respect for human dignity. In fact, Article 3 CFREU, which prescribes the prohibition of financial gain, is included within the Chapter on 'Dignity'. According to a largely accepted scholarly opinion, the principle of human dignity precludes the commodification of the human body and its parts.¹⁶

The second consideration is based on the moral value of equality between all human beings. Accordingly, the prohibition of financial gain aims at eliminating the discriminatory effects that would result of allowing markets on human body parts, because the sellers in such markets would be the most economically disadvantaged individuals.¹⁷

The third consideration is inspired by the logic of altruism and solidarity: the acts of disposition of human body parts should be based on the value of solidarity rather than self-interest,¹⁸ and therefore financial gain from the human body and its parts should be prohibited. This paper, however, maintains that a serious imbalance exists in the current distribution of the duties of solidarity and altruism

14 H. Marway *et al*, 'Commodification of Human Tissue', in H. ten Have and B. Gordijn (eds), *Handbook of Global Bioethics* (Dordrecht: Springer, 2014) 581 with further references; D. Dickenson, *Property in the body: feminist perspectives* (Cambridge: Cambridge University Press, 2007); L.A. Sharp, 'The commodification of the body and its parts' (2000) *Annual Review of Anthropology* with further references.

15 For scholarly works on contractual models for the use of human biological materials see C. Lenk and N. Hoppe, 'Using tissue and material from the human body for biomedical research: proposals for a normative model', in M. Steimann, P. Sykora and U. Wiesing (eds), *Altruism reconsidered, Exploring new approaches in property in human tissue* (New York: Routledge, 2016) 133; C. Noiville, 'Preventing conflicts of interests in the fields of human biological materials: the 'contractual model' as an avant-garde', in Steimann, Sykora and Wiesing (eds), this note above, 143; F. Bellivier and C. Noiville, 'La circulation du vivant humain: modèle de la propriété ou modèle du contrat?', in T. Revet (ed), *Code civil et modèles. Des modèles du Code au Code comme modèle* (Paris: Presses de la Sorbonne) 101; F. Bellivier and C. Noiville, *Contrats et vivants. Le droit de la circulation des ressources biologiques* (Paris: LGDJ, 2006); R. Rao, 'Genes and spleens: property, contract or privacy rights in the human body?' (2007) 35 *Journal of Law, Medicine and Ethics* 371.

16 On the ways in which human dignity is used in debates about controversial biotechnologies see T. Caulfield and R. Brownsword, 'Human dignity: a guide to policy making in the biotechnology era?' (2006) 7 *Nature Review Genetics*.

17 Marway *et al*, n 14 above 590.

18 Marway *et al*, n 14 above 593; D. Dickenson, 'Consent, commodification and benefit-sharing in genetic research' (2004) 4 2 *Developing World Bioethics*.

between the relevant actors: solidarity and altruism seem to be required only from the persons from whom human biological samples are taken (or their heirs or next of kin), but not from the commercial actors that exploit the samples. Corporations (eg pharmaceutical companies) often patent the products of research based on donated tissue or samples in order to then sell them on the market. This practice in many cases results in extensive profit for the developers of the product and no profit at all for the first transferors (donors) of the samples.¹⁹

Because of the aforementioned solidarity imbalance, this paper only focuses on non-gratuitous contracts for research and possible commercial purposes thereof. Furthermore, this paper specifically deals with contracts between the first transferor (donor) and the first transferee because the prohibition of financial gain contained in European and international documents (see section I above) is only directed to the acts of disposition between these two parties. This prohibition only concerns the human body and its parts, ‘*as such*’, which, according to the established interpretation, is an expression that refers to the human body and its parts when they have not been object of transformation.²⁰ If the first transferee of human biological samples transforms them in any way, for example by fixing them in paraffin blocks, then the material would fall outside the scope of the prohibition of financial gain. It remains uncontroverted that the transactions on human biological samples, concluded between the first transferee (insofar as the first transferee has transformed the sample) and further transferees, fall outside the scope of the prohibition of financial gain.²¹ This paper will only refer to contracts between the different transferees when necessary to analyze the imbalances in the duties of solidarity between the different contractual parties.

Sections III, IV and V of this paper correspond to the analysis of the three aforementioned considerations in relation to non-gratuitous contracts on human biological samples for the purposes of research and possible commercial uses thereof. In relation to the first consideration (respect for human dignity), section III explores the question to what extent respect for human dignity constitutes a sufficient argument for making contracts on human biological samples invalid.

19 D. Koepsell, *Who Owns you? The Corporate Gold Rush to Patent your Genes* (Oxford: Wiley-Backwell, 2009).

20 The Explanatory report to the Oviedo Convention, in relation to art 21 of the Oviedo Convention, reads: ‘(...) Technical acts (sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc) which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this Article does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such’.

21 Resta, n 13 above, 822.

On this point, this paper will address multiple understandings of human dignity. Regarding the second consideration (the moral value of equality) section IV argues that allowing markets on human biological samples would not necessarily encompass a discriminatory effect. In relation to the third consideration (the value of solidarity), section V discusses the role of this value in the sphere of research on human biological samples and possible commercial uses thereof. Section VI suggests the possible advantages of a nuanced prohibition of financial gain that allows for the conclusion of non-gratuitous contracts on human biological samples for research and commercial application of the research results. Section VII concludes this paper.

III First consideration: human dignity

One may argue that the use of the concept of human dignity in bioethics is problematic from at least two perspectives. From the first perspective, human dignity is a vague concept devoid of any specific meaning.²² Legal documents that aim at protecting human dignity in the spheres of scientific research and technology rarely provide a definition of this notion.²³

From the second perspective, human dignity is a vessel that holds multiple and, often opposed meanings.²⁴ In particular, two different conceptions of human dignity have been said to inform several supranational human rights documents: human dignity as empowerment and human dignity as constraint.²⁵ Furthermore, a different, third, understanding of human dignity has been proposed in aca-

22 R. Macklin, 'Dignity is a useless concept' (2003) 327 *BMJ* 1419–1420.

23 A.R. Chapman, 'Towards an Understanding of the Rights to Enjoy the benefits of Scientific progress and its applications' (2009) *Journal of Human Rights* 12; T. Caulfield and A. Chapman, 'Human Dignity as a Criterion for Science Policy' (2005) 2(8) *PLoS Med* 736–738.

24 For systematizations of the different meanings of dignity see: D. Schroeder, 'Dignity: One, two, Three, Four, Five, Still Counting' (2010) 19 *Cambridge Quarterly of Healthcare Ethics*; D. Schroeder, 'Dignity: Two Riddles and Four Concepts' (2008) 17 *Cambridge Quarterly of Healthcare Ethics*; N. Jacobson, 'A taxonomy of dignity': a rounded theory study' (2009) 9 *BMC International Health and Human Rights*; R.E. Ashcroft, 'Making sense of dignity' (2005) 31 *Journal of Medical Ethics* 679–682.

25 D. Beylveld and R. Brownsword, *Human dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2002) 1; S. Malby, 'Human Dignity and Human Reproductive Cloning' (2002) 6 *Health and Human Rights*. K. van Assche and S. Sterckx, 'The protection of human dignity in research involving human bodily material', in B. van Beers, L. Corrias and W. Werner, *Humanity across international law and Biolaw* (Cambridge: Cambridge University Press, 2014) 265. On a broader discussion on the concept of human dignity as a human value see: D. Feldman, 'Human Dignity as a legal value: Part I [1999] Public Law'.

demic literature: human dignity as social dignity.²⁶ According to the latter position, social dignity is conceived as the ‘right to a honourable life in terms of satisfactory material conditions’.²⁷

The following sections of this paper will briefly focus on these three conceptions of human dignity to assess whether or not human dignity is a (sufficient) reason to prohibit financial gain from human biological samples.

1 Human dignity as empowerment

The understanding of human dignity as empowerment can be traced back to the first international declarations on human rights. The UN Universal Declaration of Human Rights²⁸ is a paradigmatic example of this understanding.²⁹

This conception of human dignity derives the recognition of human rights from the intrinsic dignity of humans and attributes great importance to the protection of individual autonomy:³⁰ allowing the individual to make his/her own autonomous choices about his/her life, protects human dignity.³¹

According to this conception, by reinforcing the scope and importance of freedom of contract, the principle of human dignity should underpin (rather than limit) freedom of contract. Since individual autonomy manifests itself in the exercise of contractual choice, and since there is a widely recognized line of thinking that links respect for human dignity with respect for individual autonomy, human dignity and freedom of contract form a virtuous circle: human dignity underpins the freedom to pursue the individual’s autonomous goals.³²

26 M.R. Marella, ‘Human Dignity in a Different light: European Contract Law, Social Dignity and the Retreat of the Welfare State’, in S. Grundmann (ed), *Constitutional Values and European Contract Law* (Alphen aan de Rijn: Kluwer Law International, 2008); M.R. Marella, ‘The Old and New Limits to Freedom of Contract In Europe’ (2006) 2 *European Review of Contract Law*.

27 Marella (2008), n 26 above, 126.

28 UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III).

29 See for example the preamble and art 1.

30 The conception of human dignity as empowerment is defended for example by Patrick Capps: see P. Capps, *Human Dignity and the Foundations of International Law* (Oxford: Hart Publishing, 2009) 108. See also R. Post, ‘Dignity, Autonomy and Democracy’ (University of California Berkeley, Institute of Governmental Studies, Working Paper n 11, 2000) at < <http://escholarship.org/uc/item/8h98x8h9>>.

31 The link between dignity and autonomy can already be found in Kant. See R. O’Connell, ‘The role of dignity in equality law: Lessons from Canada and South Africa’ (2009) 2 *J•CON* 273, with further reference.

32 Beyleveld and Brownsword, n 25 above, 207.

The main criticism of the conception of human dignity as empowerment is that it is an underdetermined concept and may lead to different results in the adjudication of private disputes. In a hypothetical case where the human dignity (as empowerment) of two parties collides, it is uncertain which of the two should prevail.³³

However, the uncertainty stemming from the use of human dignity as empowerment in private law relations does not necessarily entail negative consequences. The use of open norms or general clauses like public order, public policy or good morals in the adjudication of private disputes has also a variable character, depending on the outcome of the balancing of rights and interests involved. Similarly, the role of human dignity as empowerment can be derived from the role of other human rights in contract law. Adorno argued that in order for human dignity to be functional, it needs other notions that are usually presented using the terminology of rights.³⁴ In the same vein, Beyleveld and Brownsword wrote that ‘the practical business of pressing one’s interests against others is conducted in terms of claimed human rights’.³⁵

2 Human dignity as constraint

The conception of human dignity as constraint focuses on the existence of human duties, and particularly, the duty not to compromise one’s own dignity.³⁶ Under this conception, human dignity acts as a restraint of free choice.³⁷ Here human dignity is not only seen as something intrinsic and subjective to every person, but also as the shared, objective, value that gives a community its particular identity.³⁸

³³ Marella (2008), n 26 above, 127.

³⁴ R. Adorno, ‘Human dignity and human rights as common grounds for a global bioethics’ (2009) 34 *3 Journal of Medicine and Philosophy* 234.

³⁵ Beyleveld and Brownsword, n 25 above, 13.

³⁶ Beyleveld and Brownsword, n 25 above, 37: ‘The duty to not compromise one’s own dignity is closely linked to the philosophical concept of “duties to oneself”.’ According to this concept, there is a duty not only to respect the dignity of others, but also one’s dignity. On the concept of ‘duty to oneself’ see L. Denis, ‘Kant’s Ethics and Duties to Oneself’ (1997) 78 *4 Pacific Philosophical Quarterly*; M.G. Singer, ‘On Duties to Oneself’ (1959) 69 *Ethics*.

³⁷ Beyleveld and Brownsword, n 25 above, 29.

³⁸ G. Hottois, ‘Dignity of the human body: a Philosophical and Critical approach’, in P. Kemp, J. Rendtorff and N. Mattson Johansen (eds), *Bioethics and Biolaw, vol ii: Four Ethical Principles* (Copenhagen: Rhodos International Science and Art Publishers and Centre for Ethics and Law, 2000) 95.

Explicit mentions of the need to protect human dignity, which support the conception of human dignity as constraint, are contained in the Oviedo Convention,³⁹ the CFREU,⁴⁰ and the Council of Europe's Recommendation on research on human biological materials.⁴¹ The view of human dignity as a constraint prohibiting financial gain from the human body and its parts is clearly reflected in the wordings of Articles 21 of the Oviedo Convention,⁴² Article 3 subparagraph 2 lit c CFREU⁴³ and Article 6 of the Appendix of the Recommendation on research on biological materials.⁴⁴

The prohibition on making the human body and its parts as such a source of financial gain contained in the Oviedo Convention corresponded to the intention of the Council of Europe to preclude any kind of transaction on human body parts that may give rise to an economic profit.⁴⁵ The rationale behind this consideration is that obtaining profit from transactions (ie contracts) on these materials is considered to undermine human dignity. The principle of human dignity is used in this context to preclude the commodification of the human body and its parts. Arguably, the other aforementioned supranational documents containing the same prohibition answer to the same rationale.

The conception of human dignity as constraint has been vastly criticized.⁴⁶ Firstly, scholars have submitted that this notion of human dignity comes into conflict with the individual's own sense of dignity and plays therefore a paternalistic and disciplinary role by restraining individual choices.⁴⁷ Secondly, scholars have argued that in a pluralistic society it is difficult to form a consensus on the foundations of dignity.⁴⁸ Finally, it has been maintained that it is inconvenient

39 See for example the explanatory report, the preamble, and art 1 of the Oviedo Convention.

40 'Dignity' is the title of Chapter 1 of the Charter, and the principle of human dignity is laid down in its art 1. Also art 3(c) CFREU is embedded in the 'Dignity' Chapter of the Charter.

41 See, for example, art 1 of the Appendix of the Recommendation on research on human biological materials states. 'Member States should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, the right to respect for private life and other rights and fundamental freedoms with regard to any research activity governed by this recommendation.'

42 See n 4 above.

43 See n 6 above.

44 See n 12 above.

45 See paragraph 132 of the Explanatory report to the Oviedo Convention.

46 See for example: B. Jorion, 'La dignité de la personne humaine (ou la difficile insertion d'une règle morale dans le droit positif)' (1999) *Revue de Droit Public*; J.P. Theron, 'Dignité et libertés. Propos sur un jurisprudence contestable', in *Pouvoir et Liberté: Études offertes à Jaques Mourgeon* (Bruxelles: Bruylant, 1998); Levinet, n 52 above.

47 Marella (2008), n 26 above, 131 with further references.

48 Chapman, n 23 above, 12 with further references.

that the conception of human dignity as constraint prevails over other desirable notions of human dignity such as social dignity.⁴⁹

3 Social Dignity

Marella proposed to understand human dignity as social dignity.⁵⁰ She maintained that social dignity is a ‘relational idea of dignity meant as the precondition for the individual’s self-determination and personal development, as the cultural and political implications of one’s self-reliance and self-respect, as the right to an acceptable standard of living and as a set of conditions likely to make a person a fully participant member of society’.⁵¹ Accordingly, social dignity is closely linked to the notions of liberty and equality.

According to Marella, social dignity is firmly rooted in the European constitutional traditions and the relational dimensions of private law can be found in the social meaning of the human dignity clause. In her opinion, the other understandings of human dignity (ie human dignity as empowerment and as constraint) stem from an individualist liberal mode of legal reasoning⁵² and do not take into account the redistributive results that a contract might or not produce.⁵³

However, human dignity (understood as social dignity or otherwise) is not the only relevant fundamental right or policy consideration in a contract case. Even in the cases when a contract is not contrary to the social dignity of the individual, the contract can be deemed invalid on other grounds. As Colombi Ciacchi pointed out, court and administrative decisions are not market-neutral.⁵⁴ A decision allowing non-gratuitous contracts on human biological samples because it enhances the social well-being of the transferor of the sample could foster the expansion of a market that might not be desirable for other kind of policy or moral considerations. For example, one may argue that allowing non-gratuitous contracts on human biological samples undermines equality and solidarity.

⁴⁹ Marella (2008), n 26 above, 131 with further references.

⁵⁰ Marella (2008), n 26 above; Marella (2006), n 26 above.

⁵¹ Marella (2008), n 26 above.

⁵² *Ibid* 130.

⁵³ Marella (2006), n 26 above, 274.

⁵⁴ A. Colombi Ciacchi, ‘Social Rights, Human Dignity and European Contract Law’, in Grundmann (ed), n 26 above, 159.

4 Pluralism and human dignity

In biolaw,⁵⁵ human dignity is only apparently a clear concept: it leads on occasions to completely opposite solutions⁵⁶ for the same legal-ethical problem.⁵⁷ Human dignity is a widely acknowledged principle of law but the values that fill this principle are not always clear. The determination of such values bears relevance for the assessment of whether or not a non-gratuitous contract is contrary to human dignity. Therefore, the question arises: what are the values that should fill the principle of human dignity with content?

Beyond the division between those who consider that human dignity has a subjective dimension (human dignity as empowerment), those who argue in favour of its objective dimension (human dignity as constraint), and those who argue for its social dimension (human dignity as social dignity), the notion of dignity represents at the same time at least three different but compatible ideas: dignity as an intrinsic universal value (that precludes an attack on the freedom, identity or integrity of the person), dignity as self-determination (as a means for a moral agent to decide about certain ethically relevant choices) and dignity as a social value.⁵⁸

This paper follows a pluralist approach and therefore it does not deny the understanding of human dignity as a social virtue or expression of a core of values prohibiting public or private actors' unjustifiable infringements in a person's freedom, identity or integrity. However, this paper submits that the answer to the question of what values should fill the principle of human dignity is not a universal one, but varies from person to person. In a pluralistic legal system, a regulatory definition of human dignity is inadmissible because that legal system would cease to be pluralist and would become a legal system that determines once and for all which vision or the world and of the self should be followed. In a pluralistic society, different philosophical and moral views and solutions for different bioethical problems coexist. Therefore, it is not possible to find solutions to bioethical problems by using a common and universal moral concept. Notions of ethical and legal relevance like human dignity, as has been shown, are susceptible of different and even opposed readings.⁵⁹

55 For a definition of biolaw see J. Chen, 'Biolaw: Cracking the Code' (2008) 56 *Kansas Law Review*.

56 R. Conti, *I giudici e il biodiritto* (Roma: Aracne, 2014) 33.

57 C. Casonato, 'Bioetica e pluralismo nello Stato costituzionale', in C. Casonato and C. Piciocchi (eds), *Biodiritto in Dialogo* (Padova: CEDAM, 2006) 17.

58 Conti, n 56 above, 30.

59 L. D'Avack, *Verso un antidestino* (Torino: Giappichelli editore, 2009) 13.

For these reasons, and given the plurality and variety of ethics, there is no valid argument to let one ethical position prevail over others. The individual's personal understanding of his/her own human dignity finds in the principle of pluralism a confirmation of the validity of his/her own subjective understanding.⁶⁰ It is therefore necessary to accept that every person has his/her own ethical ideas and choices, and that the practical implementation of these choices should be encouraged.⁶¹ The only limit to one's choices is the obligation to not cause damage to others.

If one wants to embrace a pluralistic and liberal vision of society and its legal system, one would have to admit that human dignity, as a universal and univocal concept, cannot be considered per se an argument against non-gratuitous contracts for research and commercial uses thereof. It is up to the person to decide, according to his/her own human dignity understanding, whether or not engaging in these kinds of transactions is detrimental to him/herself. As a consequence, a non-gratuitous contract should not be deemed contrary to the first transferor's human dignity, if he/she has manifested his/her informed consent and has freely agreed with the contractual terms.⁶²

IV Second consideration: moral value of equality between all human beings

The second consideration on which the prohibition of financial gain leans is the moral value of equality between all human beings. The ethical foundations of the value of equality have been object of a vast philosophical debate. The different scholarly positions range from utilitarianism (and consequentialism) to deontological (Kantian) perspectives.⁶³ This paper assumes that equality, independently of its ethical foundations, is a value that must be upheld in modern societies. This section focuses on the question of whether or not allowing non-gratuitous contracts on human biological samples for financial gain for the purposes of research

⁶⁰ Casonato, n 57 above, 26.

⁶¹ D'Avack, n 59 above, 13.

⁶² 'Freely' here does not refer to the mere formal freedom of contract but to substantive party autonomy. On this see A. Colombi Ciacchi, 'Party Autonomy as a Fundamental Right in the European Union' (2010) 3 *European Review of Contract Law*.

⁶³ For an overview of the different ethical justifications of the value of equality see P. Singer, *Practical Ethics* (Cambridge: Cambridge University Press, 1999).

and possible commercial uses thereof has a discriminatory effect and therefore, undermines equality.

Some scholars have maintained that the prohibition of financial gain aims at eliminating the discriminatory effects that would result from allowing markets on human body parts: the sellers in such markets would be the more economically disadvantaged individuals.⁶⁴ The first and main argument behind this consideration is that if markets on human body parts were allowed, it would be the socially disadvantaged who would sell their body parts as a means to escape from their precarious economic situation. According to this line of thought, a society should not permit that the poorer put their health at risk by selling their body parts under economical pressure whilst the richer profit from it.⁶⁵

The second common argument in support of this consideration is that the consent of poor people to accept a high health risk by selling their body parts would not be completely free because their economic situation would force them to sell in order to survive.⁶⁶ There is extensive literature debating the legitimacy of these two arguments.⁶⁷ This paper, as a general rule, deems these arguments legitimate and valid.

However, this paper submits that a distinction must be drawn between different types of human body parts. Such a distinction is necessary because the risks associated to the acts of disposition of the human body differ depending on the body part. In fact, in the case of extraction of human biological samples the health risk is, as a general rule, minimal. Not casually, obtaining financial gains from nails and hair is not prohibited.⁶⁸

One may argue that the prohibition of financial gain from body parts is directly linked to the assumption that the sellers would accept a considerable health risk because of the expectation of a considerable economic gain. However, in cases of transfer of human biological samples, the health risk is minimal.

For these reasons, obtaining financial gain from a human biological sample might provide some additional economic means to a person that is in state of poverty, enhancing his/her human dignity without considerable health risks.

⁶⁴ Marway *et al*, n 14 above; Dickenson, n 18 above.

⁶⁵ R.R. Kishore, 'Human Organs, Scarcities, and Sale: Morality Revisited' (2005) 31 *Journal of Medical Ethics* 363 with further references.

⁶⁶ *Ibid* 363 with further references.

⁶⁷ For an overview see *ibid* 363.

⁶⁸ Paragraph 133 of the the explanatory report to the Oviedo Convention explicitly excepts nails and hair from the prohibition of financial gain. Paragraph 133 reads: '(Article 21 on the prohibition of financial gain) does not refer to such products as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity.'

Allowing financial gain from human biological samples might therefore enhance equality, instead of undermining it.

V Third consideration: Solidarity

The third consideration on which the prohibition of financial gain leans is that the acts of disposition of human body parts should be based on the value of solidarity rather than self-interest.⁶⁹

Tissue and other human biological samples are often used for research with commercial purposes that in many cases results in extensive profit for the sellers of a product developed from donated tissue or samples. Furthermore, patents on genes and cell lines are constantly granted to researchers and companies.⁷⁰ By 2017 the global biotechnology market is estimated to be worth 414.5 billion dollars.⁷¹ Companies often make use of non-gratuitous material transfer agreements (MTAs)⁷² for the exchange of tissue and other human biological samples to be used in research with commercial purposes.

Whilst the argument of altruism and solidarity is strong when considering the use of human body parts for therapeutic purposes, one might claim that the same argument does not hold the same strength when it comes to the use of human biological samples for commercial purposes. It would seem as if two different standards apply to the different parties involved. On the one hand, the first transferor is prohibited from obtaining any financial gain from the use of his/her sample. In this case the standard of altruism and solidarity applies. On the other hand, companies are entitled to conclude non-gratuitous contracts (eg MTAs) on the samples that they previously obtained for free and to obtain patents on human genes. In this case, the standard of altruism and solidarity does not apply.

This paper submits that it is unbalanced to ask the first transferors of human biological samples to refrain from obtaining a financial gain from their samples, while the first and subsequent transferees of the samples do not have such

69 On the different uses of the term solidarity see D. Gunson, 'Solidarity and the Universal Declaration on Bioethics and Human Rights' (2009) 34 *Journal of Medicine and Philosophy* 241.

70 On gene patents see Koepsell, n 19 above.

71 Global Biotechnology Market by Application (Biopharmacy, Bioservices, Bioagri, Bioindustrial), by Technology (Fermentation, Tissue Regeneration, PCR, Nanobiotechnology, DNA Sequencing & Others) – Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010–2017 Report at <http://www.transparencymarketresearch.com/biotechnology-market.html>.

72 For the notion of Material Transfer Agreement see: V. Rodriguez, 'Material transfer agreements: open science vs proprietary claims' (2005) 23 *Nature Biotechnology* 2005.

restrictions. In the words of Muireann Quigley, ‘if (...) we ought not to use the human vessel as a base commercial commodity, then should this prohibition not also extend to third parties? For those who are tempted to respond in the negative to this suggestion, there remains the challenge of adequately explaining why permitting income rights is wrongful commercialisation and commodification in one instance, but not in the other?’⁷³

Under this premise, one may argue that in order to return to the first transferors of the samples a part of the benefits obtained from the commercial uses of these samples, different types of contracts could be validly concluded. This benefit sharing would enable a more balanced distribution of the duties of solidarity between the involved actors.⁷⁴

One of the models that have been applied for this purpose is the PXE benefit-sharing model.⁷⁵

In 1995 Ms Terry and her husband found out that their two children were affected by pseudoxanthoma elasticum (PXE), a rare genetic disease that causes the calcification of the skin, eyes and arteries’ elastic tissue. Later on, they saw that the researchers to whom they donated their children’s blood for the purposes of finding a cure were not willing to share it with other scientists. Moreover, the scientists studying the blood samples were able to contact only a reduced number of families affected by the same disease, and therefore, a fast significant progress was not expected to be achieved as it would be if more test persons were involved in the research.

The Terry family decided then to create a patient advocacy group: PXE International. In the course of four years they managed set up a large biorepository and began raising money for the research. The idea behind PXE International was to maintain control over research on the samples by exchanging them with researchers for a valuable consideration. Given the fact that PXE International managed to procure a vast number of samples and funding, many researchers were eager to make use of the samples collection on the terms set by PXE International. The contract between researchers and PXE International stated that the latter was entitled to any ownership rights on patents derived from the research. This condition allowed the organization to share among their members any profits arising from the discoveries, and to ensure the affordability of genetic tests.

73 M. Quigley, ‘Propertisation and Commercialisation: On Controlling the Uses of Human Bio-materials’ (2014) 77(5) *The Modern Law Review* 702.

74 On the imbalance between donors and users of human biological materials see Noiville, n 15 above 146.

75 This model has been adopted by a network of about 300 groups organised around genetic disorders. See Dickenson, n 18 above, 119 with further reference.

PXE International provided samples of blood and tissue from patients with PXE disease to scientists of the University of Hawaii. In February 2000, Charles Boyd, a University of Hawaii pathologist, isolated the gene associated with PXE. On the one hand, Dr Boyd signed the standard PXE International contract and named Ms Terry as part of the research team on the patent application. On the other hand, however, Dr Boyds' contract with the University of Hawaii granted the university the rights to his inventions.

This case did not reach the courts: the parties concluded an agreement on 2001, whereby PXE International maintained the right to take the licensing decisions, and the profit deriving from marketable products were to be split between both parties. The patent was granted in 2004.

The PXE International model is just an example of how the conclusion of non-gratuitous contracts may result in a more balanced distribution of the benefits of scientific research. Depending on the kind of research, other models could be designed to distribute such benefits while fostering at the same time the protection of the first transferor's rights.

VI Possible advantages of a nuanced European prohibition of financial gain

If human dignity, equality, solidarity and altruism are not sufficient reasons for prohibiting non-gratuitous contracts on human biological samples between the first transferor and the first transferee for the purposes of research and commercial uses thereof, then the question arises of whether it is desirable to establish a nuanced ban on obtaining final gain from the human body and its parts, that allows for the conclusion of such contracts.

A lightened prohibition of financial gain is desirable both from a theoretical and from a practical perspective. From a theoretical perspective, a prohibition of financial gain that does not include non-gratuitous contracts on human biological samples allows for the expansion of the sphere of personal freedom and autonomy.

In a liberal society, the legislator should refrain, inasmuch as possible, from prohibiting a priori behaviour that falls within the realm of private autonomy.⁷⁶ On the contrary, the State should grant the appropriate conditions for the implementation and development of personal choices.

⁷⁶ On a liberal theory of contract law see T. Gutmann, 'Some preliminary remarks on a liberal theory of contract' (2013) 76 *Law and Contemporary Problems*.

From a practical perspective, contract law and contracts constitute the instruments for the implementation, development, and protection of the person and his/her personal choices.⁷⁷ If contracts in general, and non-gratuitous contracts in particular are allowed, the transferor could be not only granted statutory protection (eg data protection laws, informed consent laws) but also all the contractual protection stemming from contract law or from the contract itself.

Legal scholars have already identified some advantages that a contractual model could have over other models (proprietary or informed consent models) for the use of human biological samples:⁷⁸ a contractual model may contribute to the rebalancing of the relationship between the first transferor and the transferees; it could help organizing the circulation of human biological samples⁷⁹ and it may prevent researchers' conflict of interests.⁸⁰

In addition to these advantages, perhaps the most evident practical benefit of allowing non-gratuitous contracts on human biological samples is the possibility for the first transferor of obtaining a direct economic benefit from the transfer of the sample. One could imagine different types of contracts for the transfer of the sample in exchange of an economic remuneration.

The contract of sale comes first to mind, but other contracts, as a non-gratuitous lease of use could be perfectly suitable for the regulation of the use of human biological samples, in addition, of course, to all the atypical contracts imagined by the parties (eg PXE International) for the distribution of the benefits arising from the research. One can also imagine contracts whereby obtaining an economic remuneration for the transfer of the sample is conditioned to a positive outcome of the research or to the amount of the actual economic profit obtained from the findings of the research.

Depending on the type of contract, the parties could attach conditions (precedent and subsequent), terms and limits to the use of human biological material. Furthermore, depending on the law of the country, different contractual remedies could be available in case of breach of the contract. Illegality, public order and public policy could constitute the grounds for the nullity of a contract in the cases where, for example, the research project does not meet the necessary ethical requirements. Furthermore, contractual categories like duress, mistake and fraud, could be used to invoke the nullity or annulability of the contract when the consent of one of the parties is not perfect.

⁷⁷ On the contract as a mechanism for governance see F. Möslin and K. Riesenhuber, 'Contract Governance – A Draft Research Agenda–' (2009) 5 *European Review of Contract Law*.

⁷⁸ Noiville, n 15 above, 145.

⁷⁹ *Ibid* 147.

⁸⁰ *Ibid* 148.

Moreover, the parties of the contract could agree, among other things, on the period of use of the sample, the limitations for transferring the samples to third parties, the types of research that can be carried on the sample (commercial, academic, for a specific disease, for several diseases, etc) and the procedures to follow in case of unexpected findings.

Finally, contracts (non-gratuitous and gratuitous) on human biological samples have the advantage that they do not ignore the requirements of informed consent. On the contrary, if these types of contracts are allowed, informed consent could constitute a fundamental element for the formation and validity of such contracts.

VII Conclusion

This paper submits that the policy considerations behind the regulation of the uses of human body parts should vary depending on the type of human body part and the purposes for which the part is to be used. In particular, this paper sustains that the considerations behind the prohibition of financial gain do not necessarily apply to contracts on human biological samples for research purposes and commercial uses thereof.

Regarding the first consideration (human dignity) this paper concludes that a universal, common and univocal concept of human dignity is contrary to the principle of pluralism and to the autonomy of the person. In a liberal and pluralistic society, the content of the principle of human dignity should be filled by the person's own vision of his/her own human dignity. Accordingly, if the first transferor of a human biological sample freely agreed to the content of contract and was duly informed about its consequences, the contract cannot be considered invalid on the grounds of a violation to human dignity.

Regarding the second consideration (equality), this paper argues that the risk of discrimination against economically disadvantaged individuals arising from the possibility of obtaining financial gain from the human body and its parts hardly exists in the case of non-gratuitous contracts on human biological samples. The prohibition of obtaining financial gain from the use of the human body and its parts is directly linked to the fact that the persons obtaining the gain would not have accepted a considerable health risk in the absence of the future economic gain. As a general rule, the transfer of a human biological sample does not represent a considerable threat to the transferor's health. Obtaining financial gain from a human biological sample might provide some additional economic means to a person that is in state of poverty. Allowing financial gain from human biological samples might therefore enhance equality, instead of undermining it.

Regarding the third consideration (solidarity), this paper sustains that the use of human biological samples for commercial purposes creates unbalanced duties of solidarity whereby the first transferor of the sample is not entitled to any financial gain, whilst the transferees are allowed to obtain very considerable financial gains. In order to better distribute the solidarity duties, it would be desirable to allow non-gratuitous contracts to return to the persons that transferred the samples a part of the benefits obtained from the commercial uses of these samples.

Since human dignity, equality and solidarity do not constitute sufficient reasons to consider invalid non-gratuitous contracts on human biological samples for research and commercial it would be desirable to establish a more nuanced European prohibition of financial gain that allows the conclusion of non-gratuitous contracts on human biological samples for research and commercial uses thereof.

A lightened prohibition of financial gain would allow the first transferor to obtain direct economic benefits from the transfer of the sample and would facilitate the distribution of the benefits arising from the research. Moreover, the contractual parties could freely establish the conditions and terms for the use of the sample in the research while at the same time having available all the remedies arising from contract law and the contract itself.