Nanotechnologies, bioethics and human dignity

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SUMMARY

Nanoscale science, research, and technology present a complex set of circumstances. First of all, this field involves many different subjects, including biology, chemistry, physics, and environment sciences. Secondly, although scientists are working increasingly at a molecular level, nanotechnology is about much more than a reduction of scale. Indeed, nanoscience and Nanotechnologies offer an unprecedented ability to control and manipulate nature, offering hope for progress.

Ethical perspectives vary considerably in this field, but commentators and researchers share a concern about a specific worrisome issue: the lack of appropriate ethical and legal principles and processes (associated with issues including health risks, human body manipulation, and private life violation), to guide nanotechnological R&D, commercialization, and final use. Some authors partially reject this concern by suggesting that Nanoscience and Nanotechnologies do not constitute an autonomous category, and that they are instead just the operative result of combining other traditional areas of study. However, the nanotechnological debate brings up the semantic and content issues of bioethics and foments a contentious discussion emphasizing human dignity. Issues include enhancement versus therapeutic intervention, traceability versus privacy, and societal benefits versus risks.

From these preliminary considerations, we will move on to discuss (I) the traditional, although still controversial, relationship between bioethics and human dignity, and (II) return to the subject of nanotechnology. We will discuss how today in Europe, although still indefinite, the principle of respect for human dignity is a welcomed contributor to "ethical vigilance" about the uncertain development of new nano-scale technologies. We will also note how U.S. strategy in this regard is simply lacking and appears only as a purely discursive "key issue in long term".

Key-words: Nanotechnology, Social control over science, Science, Technology, Dignity, Precautionary principle, Social representation, Government financing, Profits, Future of mankind, International law, United States, European Union, Progress, Convention on Human Rights and Biomedicine,Universal Declaration on the Human Genome and Human Rights, Human rights, Protection of rights, Research policy.

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RÉSUMÉ

NANOTECHNOLOGIES, BIOÉTHIQUE ET DIGNITÉ HUMAINE

La science, la recherche et la technologie à l'échelle de la nanotechnologie présentent une série complexe de circonstances. Tout d'abord, ce domaine couvre de nombreux sujets différents, comprenant la biologie, la chimie, la physique et les sciences de l'environnement. Deuxièmement, bien que les scientifiques travaillent de plus en plus au niveau des molécules, la nanotechnologie ne se résume pas à une réduction d'échelle. En effet, la nanoscience et les nanotechnologies nous offrent la possibilité sans précédent de contrôler et de manipuler la nature, ce qui nous permet d'espérer progresser.

Les perspectives éthiques varient énormément dans ce domaine, mais les commentateurs et les chercheurs se font du souci concernant une question particulièrement inquiétante : le manque de principes et de procédés éthiques et juridiques appropriés (ainsi que des questions comprenant les riques pour la santé, la manipulation du corps humain, et la violation de la vie privée), pour guider la recherche et le développement, la commercialisation et l'utilisation finale des nanotechnologies. Certains auteurs rejettent ce souci en partie en suggérant que la nanoscience et les nanotechnologies ne constituent pas une catégorie autonome, et qu'elles ne sont que le résulatat opérationnel de la combinaison d'autres domaines d'étude traditionnels. Cependant, le débat nanotechnologique pose les questions sémantiques et les questions de contenu de la bioéthique et nourrit le contentieux qui souligne la dignité humaine. Les problèmes comprennent l'amélioration contre l'intervention thérapeutique, la traçabilité contre la vie privée, et les bienfaits pour la société contre les risques.

Après ces considérations préliminaires nous discuterons (I) de la relation traditionnelle, bien que toujours controversée, entre la bioéthique et la dignité humaine, et (II) nous reviendrons vers le sujet de la nanotechnologie. Nous examinerons comment aujourd'hui en Europe, bien qu'encore mal défini, le principe du respect de la dignité humaine est bienvenu en tant que contribution à la « vigilance éthique » concernant le développement incertain des nouvelles nanotechnologies. Nous noterons également comment la stratégie des USA à cet égard manque tout simplement et ne paraît que comme « une question clé dans le long terme » purement discursive.

Mots-clés : *Nanotechnologie, Contrôle social de la science, Science, Technologie, Dignité, Principe de précaution, Représentation sociale, Financement par le gouvernement, Profit, Devenir de l'humanité, Droit international, États-Unis, Union européenne, Progrès, Convention sur les droits de l'homme et la biomédecine, Déclaration universelle sur le génome humain et les droits de la personne humaine, Droits de l'homme, Protection des droits, Politique de la recherche.*

1. INTRODUCTION

Reflecting on the relationship between nanotechnology, bioethics and human dignity entails more than this introduction.

On the one hand, from a formal point of view, we see that these three concepts are characterized by semantic ambiguity, because they have different meanings depending on their cultural contexts. In other words, the meaning of each of these concepts varies depending on the issue in question.

On the other hand, each of these concepts has seen a gradual increase in debates about what its limit(s) should be, and these debates are now very fervent. The technique[1] as a scientific mode of has made it possible to intervene on the human being, directly or indirectly,

1. For a definition of the technique, see L. MUMFORD, *Technics and Human Development: Myth of the Machine*, vol. 1, Harcourt Brace Jovanovich Publishers, New York, 1967. We are not as interested here in considering the criticisms over time attributed to the theory adopted by the Author, by some identified as being too near to technisism, sometimes even as antitechnicistic. In this context it is enough to recall the proposed distinction between equipments, instruments and machines (see here V. DUSEK, *Philosophy of Technology: An Introduction*, Blackwell Publishing, Oxford, 2006, p. 26 et seq.). Moreover, it is interesting the way the Author emphasizes the relationship between man and technique, which makes man different from animal. This big difference is called *symbol-creating ability*. With the human body, and through language, man enables creative and virtuous development processes (see L. Mumford, *Technics and Human Development*, cit. p. 59 et seq.)

and this creates an increase in scientific, medical, philosophical, ethical, legal, and social questions about the legitimacy and the legality of those actions. Furthermore, when science and its applications, techniques and technology (biomedical first, even nano-biomedical today), are uncertain, we use the precautionary approach[2]. The UE legal system has interpreted and converted this into a legal principle, and different national legal systems of Europe have *stricto sensu* formalized it in law[3].

Today there is an absence of relevant case law for nanotechnology. In the hope of intervening before the courts must do so to make repairs, self-regulation tools are implemented. When there is space for ethical principles, human dignity, and its legal protection. these self-regulation tools (in the form of codes of conduct, value guidelines, etc.) are implemented.

From these preliminary considerations, we use the uncertainties regarding nanotechnology to (I) move from the more traditional, although still controversial, relationship between bioethics and human dignity, and (II) return to the subject of nanotechnology. Today in Europe the principle of respect for human dignity is still indefinite, but it is nonetheless a welcomed contributor to « ethical vigilance » about the uncertain development of new nano-scale technologies. However, U.S. strategy in this regard is simply lacking and appears only as a purely discursive "key issue in long term".

2. BRIEF EXCURSUS OF UNCERTAIN DEFINITIONS

As noted by C. WEILL, the transition from using the traditional optical microscope to Near Field Optical Microscopy occurred in order to investigate the optical behaviour of a single molecule[4].

In parallel, the process of miniaturization and the development of electronics[5] and physics and quantum encryption has opened the economic and political *nouvelle vague,* to create what are considered to be "nanotechnologies".

Especially when they are presented to an audience of non-experts, nanotechnologies are oversimplified as being

2. Inspired by a German principle (*Vorsorgeprinzip*) and offered for the first time as a mere suggestion to the World Charter of Nature of 1982, the concept of precaution has received a first definition in the Rio Declaration on Environment and Development 1992. The Declaration refers to a "precautional approach", in political rather than legal terms, although in "principle" No 15 of the Declaration, it states "*where there is a risk of serious or irreversible damage, lack of absolute scientific certainty should not serve as a pretext for postponing the abolition of the appropriate and effective, also in relation to costs, intended to prevent degradation environment*". Following the declaration, some treaties and numerous acts of soft law have been referred to as the "precautionary principle", and sometimes seen as legally relevant under a formal point of view (for example, think of the UN Framework Convention on Climate Change of 1992 whose Article 3 places an ethical and a political duty on the Parties to take precautionary measures "*to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects*". The same approach has been adopted in a) the UN Convention on Biological Diversity (CBD), negotiated at the Earth Summit in Rio de Janeiro in 1992; b) in the Rio Declaration, whose Principle 15 codified for the first time at the global level the precautionary approach, which indicates that lack of scientific certainty is no reason to postpone action to avoid potentially serious or irreversible harm to the environment; c) the Helsinki Convention on protection and use of transboundary watercourses and international lakes (1992), which obliges the Parties to apply the precautionary principle). The concept of precaution acquires importance in international trade law as justification for measures restricting the freedom of trade, notably through the work by reference. 5.7 of the SPS (Agreement on Sanitary and Phytosanitary Measures), which states that, in the absence of sufficient scientific evidence, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information (on this theme see A. BIANCHI, M. GESTRI, *Il principio precauzionale nel diritto internazionale e comunitario*, Giappichelli, Milan, 2006 and S. DI BENEDETTO, *La funzione interpretativa del principio di precauzione in diritto internazionale*, in *Dir. Comm. Internaz.*, 2006, p. 321 et seq.). From the point of view of EU law, however, note how, after decades of case law of the EU Court of Justice and after the Treaty of Maastricht, the precaution has found its place in art. 130r (now 174) of the EC Treaty with regard to environmental policy. It is interesting to note that this article specifically mentions a "*precautionary approach*". This stresses the reference to a methodological plan. Far from giving a definition of the principle, the Treaty has included it in the other principles of EU environmental policy.
3. Think of France, which has constitutionalised the precautionary principle. See R. VANNEUVILLE, S. GANDREAU, *Le principe de précaution saisi par le droit: les enjeux de la sociopolitiques du principe de juridicisation précaution*, Report delivered to the Ministry for Ecology and Sustainable Development, Paris, La Documentation française, 2006. See S. DESMOULIN, "Évolution du droit et développement des nanotechnologies", in *ADSP*, No 64, 09/2008, pp. 71-73, which puts in evidence the relationship existing between the precautionary principle and nanotechnologies.
4. C. WEILL, "Nanosciences, nanotechnologies et principe de précaution", in *Les cahiers Droit, Sciences et Technologies*, CNRS Editions, Paris, 2007.
5. Cfr. G. SCHMID, M. DECKER, H. ERNST, H. FUCHS, W. GRÜNWALD, A. GRÜNWALD, H. HOFMANN, M. MAYOR, W. RATHGEBER, U. SIMON, D. WYRWA, *Small Dimensions and Material Properties: A Definition of Nanotechnology*, Europäische Akademie zur Erforschung von Folgen wissenschaftlich-technischer Entwicklungen, Graue Reihe, n. 35, 11/2003, p. 8.

simply a matter of size[6] or they are hidden behind broader argumentative speculation about technological convergence[7]. This causes them to become matters of imagination[8] and a source of human fear[9].

It is stated that the objective of nanotechnology is to study and develop functional systems and devices whose properties are controlled by materials at the nano-scale. Multifunctional materials – molecules and

6. For example, the U.S. Federal NNI (National Nanotechnology Initiative) defines nanotechnology as follows: "*The essence of nanotechnology is the ability to work at the molecular level, atom by atom, to createlarge structures with fundamentally new molecular organization. Compared to the behavior of isolated molecules of about 1 nm (10-9 m) or of bulk materials, behavior of structural features in the range of about 10-9 to 10-7 m (1 to 100 nm - a typical dimension of 10 nm is 1,000 times smaller than the diameter of a human hair) exhibit important changes. Nanotechnology is concerned with materials and systems whose structures and components exhibit novel and significantly improved physical, chemical, and biological properties, phenomena, and processes due to their nanoscale size. The goal is to exploit these properties by gaining control of structures and devices at atomic, molecular, and supramolecular levels and to learn to efficiently manufacture and use these devices. Maintaining the stability of interfaces and the integration of these "nanostructures" at micron-length and macroscopic scales are all keys to success*" (pp. 19-20). At the same level, the EU Commission gives a definition of what can be considered to be a "nanotechnology": "*Originating from the Greek word meaning "dwarf", in science and technology the prefix "nano" signifies 10-9, i.e.one billionth (= 0.000000001).One nanometre (nm) is one billionth of a metre, tens of thousands of times smaller than the width of a human hair. The term "nanotechnology" will be used here as a collective term, encompassing the various branches of nanosciences and nanotechnologies. Conceptually, nanotechnology refers to science and technology at the nanoscale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. Such properties can then be observed and exploited at the micro- or macro-scale,for example, for the development of materials and devices with novel functions and performance*".
7. CNIL, Nanotechnologies, Informatique et Libertés, Communication Ph. Lemoine, 12.01.2006. The report lists the scientific disciplines involved in the NBIC convergence. Note that many nanotechnologies descend from the physics and its experimentations: "*Physique (nano) : découverte en 1985 par Richard Smalley (Prix Nobel 1996) d'un nouvel état de la matière, le carbone C60, dont la structure cristalline permet, en se complexifiant, de fabriquer des « nanotubes » 100 fois plus résistants que l'acier, 100 fois moins denses et dotés d'une supraconductivité exceptionnelle ; Biotechnologies (bio) : avancées rapides dans la production de la vie à partir de la non-vie, avec la mise au point de nouveaux codes génétiques. Une cellule disposant d'un code génétique à 2 lettres a ainsi été produite ; elle est considérée comme « vivante » car dotée de propriétés d'autoreproduction et d'autocomplexification. TI (info) : travaux sur l'ordinateur quantique en utilisant les propriétés d'intrication de la physique quantique, dans laquelle un évènement peut à la fois s'être produit et ne pas s'être produit (superposition d'états) ; Sciences cognitives (cogno) : invention du microscope à effet tunnel en 1984 par 2 ingénieurs d'IBM (Gérard BINNIG et Heinrich ROHRER, prix Nobel 1986), permettant de voir et de manipuler à l'échelle nano. Même s'il s'agit de la mise au point d'un instrument de connaissance, cette invention ressort plus de la physique que des séries cognitives proprement dites"* (p. 5).
8. For discussion of the role of science-fiction in the public debate on nanotechnology, refer to Micro & Nano Alliage magazine (No. 62, 04/2008). In particular, see P. PAJON, *La communication des nanotechnologies : un bricolage culturel* et R. HOFFMANN, *Donner sens aux images du nanomonde*. We appreciate the first Author's speculations. An anthropologic point of view seems to emerge, which highlights: "*Dans La pensée sauvage, Lévi-Strauss décrit le bricolage comme une «incessante reconstruction à l'aide des mêmes matériaux, (…) d'anciennes fins (…) appelées à jouer le rôle de moyens : les signifiés se changent en signifiants, et inversement ». L'objet fini perd la fin d'origine pour devenir matériau de construction dans un autre projet. Ce souci de « récupération » peut être utilisé comme symbole d'un besoin humain fondamental : celui de créer du sens, en tissant entre des objets, souvent en apparence hétéroclites, des rapports signifiants. Selon Lévi-Strauss, les mythes, et la pensée mythique, opèrent en effet sur le plan spéculatif de la même manière que le bricolage sur le plan pratique: « La pensée mythique dispose d'un trésor d'images accumulées par l'observation du monde naturel : animaux, plantes, avec leurs habitats, leurs caractères distinctifs, leurs emplois dans une culture déterminée. Elle combine ces éléments pour construire un sens, comme le bricoleur, confronté à une tâche, utilise les matériaux pour leur donner une autre signification, si je puis dire, que celle qu'ils tenaient de leur première déstination*". Starting from the anthropological meaning of the cultural pluralism (the "*bricolage culturel*"), the A. explains the heterogeneous field of nanotechnologies. Payon considers that a) the metaphor of the convergence, b) the imaginary built around that, and c) the activity of the "mythological recycling" poses the communication expedient method for the recent standards. See also M. MAESTRUTTI, "Making the invisible visible. The role of vision and image in the construction of a history of nanotechnology", in *Rivista Italiana di Sociologia*, n. 3, Jul.-Sept. 2008, pp. 427-450).
9. See B. BENSAUDE-VINCENT, *Se libérer de la matière. Fantasmes autour des nouvelles technologies*, cit, The idea of manipulating atoms, the elements that make up matter, has become a reality. In this way nanotechnology is rhetorically defined as a broad project to control the structure of matter. The reduction of matter, and the desire for it to be effectively reduced, seems to be necessary to better performances of materials. The Author stresses in her book that matter is an abstract concept which has been gradually adapted to the conditions posed by Western science (see p. 40 et seq.). From a sociological and epistemological point of view, the materiality is a "*complex hybrid*" that can be contextualized and defined similar to how its opposite, the concept of dematerialization, can be. This complexity allows man to escape the deterministic drift. To this extent, to escape matter is illusory and dangerous. Born in the '80s from an economic consideration (less matter was consumed: less steel, less cement, less glass), dematerialization is for the Author an ethnocentric opportunism (because it would concern only the industrialized countries) and it is difficult to test its efficacy (because the obsolescence of materials and tools cannot be avoided). The Author passes through disciplines such as geography and ecology to refute their comments on this subject, and introduce the theme of new technologies. In this context, every discourse on nanotechnologies is program-oriented: any object can be (or will be) created at the nanoscale! Determinism then becomes socially funded, as well as anthropologically, geographically and ecologically implicated (the metaphor of "*homo faber*" is concerned here): "*Les Prométhées modernes entendent fabriquer un monde nouveau à partir des briques élémentaires*" (p. 37). To overcome this impasse, the Author proposes a reading of the materials science&engineering, and proposes a solution: "*On peut réinterpréter tous ces discours sur la dématérialisation et les renverser en montrant qu'en aucun cas il ne s'agit d'une libération de la matière. […] Il s'agit selon moi d'une nouvelle attention aux puissances inhérentes à la matière, […] une forme de contrat que les humains passent, non avec la matière en général mais avec les matériaux, c'est-à-dire des singularités*" (pp. 39-40). On the one hand this would avoid the unnecessary attempt to destroy the existing and necessary borders between science and technique and, on the other hand, would take into consideration the "human project".

biomolecules, nanoparticles, clusters – designed for self-assembly[10], can be used in nanofabrication processes called *bottom-up*. Recently, in the process of designing, testing and manufacturing, we have also come to a method called *top-down*. In this method one attempts to interact with ever-smaller structures, starting by improving resolution and performance of macro-microscopic equipment that is used for handling materials[11].

This introduction to the subject cannot discredit what is meant by nanotechnology. Nor can this general consideration determine with certainty the definition of nanotechnology, or make nanotechnology an autonomous scientific discipline. Even distinguished authors like J. SCHUMMER have stressed that definitions remain swinging according to the approach – nominal, realistic or teleological – and are adopted to explain contents and implications[12].

To speak, write, or comment on nanotechnology is economic and political, before scientific: first, we are giving a name to what is fictitious[13] so as to bring it closer to reality and fill it with possibility (even theatrics[14]), and second, we are renaming what already exists to make it new and innovative[15], and thus competitive.

Nanotechnology encourages research and development (R&D), aimed at controlling the fundamental structure and behaviour of matter. The European Commission expressed the following: *"The applications of nanotechnology are emerging and will impact on the lives of all citizens [...] The potential of nanotechnology has prompted many countries to undertake R & S programs which benefit from substantial government investment and rapid growth. Over the past ten years the interest in nanotechnology has seen an extraordinary increase, as evidenced by public investment, passed rapidly from 400 million in 1997 to the current more than 3 billion euros."*[16].

10. For example, in relation to nanomaterials, on 05.04th.2007 the Almaden Research Center's computer and the IBM TJ Watson Research Center announced that it has created Airgap, a pattern of electrical insulation. The product, still being tested, would be able to create billions of interstices between the semiconductor material and the copper. This would accelerate the speed of a conventional microprocessor by 35% and would help create laboratories on chip. Going from nanoelectronics to chemistry, the criteria of self-conductivity are parallel with countless applications that work on the subject, rather than on the process: cell regeneration, molecular therapy, drug delivery, etc.. On the latter profiles, see introductory texts such as V. BALZANI, A. CREDO, M. VENTURI, *Molecular Devices and Machines. A Journey Into the Nano World*, Wiley-VCH, Weinheim, 2003. About the relationship between observation of nature, and biological behaviors of nanobiotechnologies cf. D. S. GOODSELL, *Bionanotechnology. Lessons from Nature*, Wiley, Hoboken, 2004.
11. Many texts, articles, reports, which have been published at a national and international level, move from the same consideration. For example, see M.-A. GRIMAUD, C. HERVE, B.-M. KNOPPERS, P.A. MOLINARI, G. MOUTEL, Les *enjeux des nanotechnologies éthiques*, Dalloz, Paris, 2007, as well as the oldest Report DUPUY J.-P., F. ROURE, *Les nanotechnologies: éthique et prospective industrielle*, Paris, 2004 (available at http://www.cgm.org/themes/deveco/develop/nanofinal.pdf).
12. See among many others J. SCHUMMER, "Identifying ethical issues in nanotechnologies" in A.M.J. HENK TEN HAVE (eds.), *Nanotechnology: Science, Ethics and Politics*, UNESCO Publishing, Paris, 2007, pp. 79-98. Among the many reports that various countries have issued on the topic of ethics of nanosciences and nanotechnologies,we refer to the Report issued by The Royal Society & The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties* (07.29th.2004), which is both the more traditional and still exemplary. In Italy, the National Bioethics Committee has recently delivered its *Report on Nanosciences and Nanotechnologies*, adopted on 09.06.2006. The French Ethics Committee published its *Enjeux éthiques des nanosciences et des nanotechnologies* (http://www.cnrs.fr/fr/presentation/ethique/comets/index.htm). Compared with Italy, France is a very interesting case, since a real debate has been produced at a parliamentary level during the last years. For example, see No Report 1588 of LORRAIN J.-L., D. RAOUL, Office Parlamentaire d'évaluation des choix scientifiques et technologiques, *Nanosciences et progrès médical*, filed on 05.06th.2004 (http://lesrapports.ladocumentationfrancaise.fr/BRP/054000313/0000.pdf). In France the debate has been developed among the Ministry-level Agencies. This has produced many thematic and specialized reports. We mention here that drafted and published in 2006 by the Comité de la Prévention et de la précaution, Ministère de l'écologie, du développement et de l'aménagement durables, *Nanotechnologies, nanoparticules: quels dangers? quels risques?*
13. A. NORDMANN, "Social Imagination for Nanotechnology", in European Commission, *Nanotechnology: A Preliminary Risk Analysis on the Basis of a Workshop*, Community Health and Consumer Protection, Brussels, 03.1st-2nd.2004, pp. 111-113. See also C. LAFONTAINE, ''Les nanotechnologies: de l'imaginaire scientifique aux transformations culturelles'', in M. VENNE and M. FAHMY (dir.). *L'annuaire du Québec 2007*, Fides, Montreal, 2006, pp. 293-94.
14. See M. MAESTRUTTI, *Who's afraid of nanotechnology? The role of fiction in situations of uncertainty*, paper presented at the Second National Conference STS Italy: Capturing Proteo. Technoscience and knowledge society in Europe, University of Genoa, 06. 19th-21st.2008 (available at www.stsitalia.org/papers2008).
15. In one of its brochures, the NNI offers the reader this scenario: "*Imagine a single area of scientific discovery with the potential to enable a wealth of innovative new technologies across a vast array of fields including healthcare, information technology, energy production and utilization, homeland security and national defense, biotechnology, food and agriculture, aerospace, manufacturing, and environmental improvement. Nanoscience, the study of the unique properties of matter that occur at extremely small scales, has this potential*". This communication uses typical marketing techniques to persuade consumers. It creates familiarity with nanotechnology and helps reaching a wide consensus, thus facilitating the governance of U.S. intentions in the field of nanotechnology.
16. EU Commission Communication, *Towards a European strategy for nanotechnology*, COM/2004/0338 final. (http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus! prod!DocNumber&lg=it&type_doc=COMfinal&an_doc=2004&nu_doc=338).

Information technology, optics, telecommunications, chemistry, physics, medicine, cognitive science, and biotechnology were all affected by this change[17]. In May 2008, J. F. SARGENT, Specialist in Science and Technology Policy Resources, Science, and Industry Division, suggested nanotechnology to members of Congress as part of the need to increase U.S. competitiveness: *"The United States launched the first national nanotechnology initiative in 2000. Since then, more than 60 nations have launched similar initiatives. In 2006, global public investment in nanotechnology was estimated to be $ 6.4 billion, with an additional $ 6.0 billion provided by the private sector. More than 600 nanotechnology products are now in the market, generally offering incremental improvements over existing products. However, proponents maintain that nanotechnology research and development currently underway could offer revolutionary applications with significant implications for the U.S. economy, national and homeland security, and societal well-being. These investments, coupled with nanotechnology's potential implications, have raised interest and concerns about the U.S. competitive position"*[18].

In this context:

- In the EU and the U.S. the political-institutional language of nanotechnology is often fed by utilitarian semantics;
- The analysis of the relationship between science and norms (ethics as much as legal-policies) has radically changed the past institutional approach (often by means of case law). Previously, the regulation of science was based on the technical notion of its alleged neutrality. Then a "co-production" approach has linked science and law[19].

Scientific policies, science itself and the law, are all dynamic social institutions. We must ask ourselves about how each of these institutions defines their responsibilities in the field of nanotechnology. The overwhelming speed of progress and research and the need to meet market needs are at the same time both epistemic and social. Starting from this question, bioethics enters into a relationship with nanotechnology which is presented to the public today as a technological fracture.

3. FROM THE UNCERTAIN DEFINITIONS TO THE APPLICATION OF NANOTECHNOLOGY. THE NON-EXISTENCE OF LAW AND BIO-ETHICS OF NANOTECHNOLOGY

It would be impossible to enumerate all of the ethical implications of nanotechnology in the short space allowed. Instead, we will focus our attention on the relationship between the concepts of nanotechnology and human dignity.

In order to bring these two concepts together, we underline an epistemological point, which is that studies of nanotechnology highlight the traditional debate on the natural-artificial dichotomy and, through the neoliberal approach, relaunch the ontological fluidity among human nature, nature and techniques.

Moreover, nanotechnology is defined as a "disruptive technology". This does not only indicate the new processes and new techniques whose implementation causes a relevant impact on traditional and older technologies. Distinguished authors[20] have highlighted how the nanotechnology process revives the perfectionist paradigm[21] and the old Promethean myth of possession, the domination of man over nature and its knowledge.

It has been also clarified that the nanotechnology process feeds a reductionist argument.[22] To manipulate

17. So much has been stressed when the European Commission adopted an Action plan for Europe 2005-2009. In it were set out measures for the immediate operation of a *"safe, integrated and responsible"* N&N (Nanosciences and Nanotechnologies) (06. 07th.2005, COM (2005) 243 fin).
18. F. SARGENT, *Nanotechnology and U.S. Competitiveness: Issues and Options,* CRS Report for Congress, 15 March 2008, (available on the Internet at http://www.fas.org/sgp/crs/misc/ RL34493.pdf).
19. Cfr. M. TALLACCHINI, "La costruzione giuridica della scienza come coproduzione tra scienza e diritto", in *Politeia*, XVIII, 65, 2002, pp. 126-137. More recently, also norms, such as the voluntary initiatives for corporate responsibility, have been involved in the same process.
20. P. LIN, F. ALLHOFF, "Untangling the debate: The ethics of human enhancement", in *NanoEthics: Ethics for Technologies that Converge at the Nanoscale*, December 2008, Vol. 2, Number 3, pp. 251-264. The A. affirm that "*the fiercest resistance to human enhancement technologies is perhaps a concern about their effect on "human dignity" and what it means to be human*" (p. 261). This lead us to say that ethical issues raised by enhancing technologies concern a) the technologies themselves, b) the effects of the enhancement on those who are enhanced, c) the traditional, existing relationship between human and non-human.
21. Cf. M. SANDEL, *The case against perfection: Ethics in the age of genetic engineering*, Belknap, Cambridge, MA, 2007.
22. Cf. J. C. SCHMIDT, "Unbounded Technologies: Working Through the Technological Reductionism of Nanotechnology", in D. BAIRD, A. NORDMANN, J. SCHUMMER (eds.), *Discovering the Nanoscale*, IOS Press, Amsterdam, 2004, pp. 35-50.

matter at the molecular scale implies a kind of "naturalization" of the technological process. Therefore the nature-artifice dichotomy is progressively blurred.[23]

From an anthropological point of view, man is involved yet again in new biomedical techniques[24], and concerned with the "nanotechnology revolution"[25].

The nature-artifice debate is present in debates on nanotechnology- an example is the debate about improving human performance. It should be remembered that this debate about the relationship between man and technology[26] is quite old; it could be seen strongly in the eighteenth and the nineteenth century. Due to its age and complexity, exploring the relationship between man and the technoscience takes more than a review of the development of cotton spinning and the steam engine[27]. Out of this complex history, what we see today is an inextricable relationship between technique and science[28] in which technical and scientific fields come together to develop new creative technologies.

This relationship between man and technology has manifested differently over time. At times it has produced fear of the risks of new technology, and at other times it has produced the tendency to consider the profitability of a man-technology alliance[29]. As already affirmed, it is difficult to imagine a distinctive man-science-technology axis. The considerations that come up in this area include the findings of innovation, the degree of involvement of human technology on the human body,[30] and the level of ownership that one feels towards the technological object.

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23. It seems appropriate to point out an example from the subject of nanobiotechnology which reflects the opposite outcome of the described trend: DUPUY J.-P., "Quand les technologies convergeront", in *Revue du Mauss* 2004-1, n. 23, pp. 408-417. About the nanobiotechnological convergence, the A. takes into consideration the "natural nanotechnology" (i.e. the biological nanotechnology) to introduce the nanotechnology's metaphysical research program and to criticize the very first aim of nanobiotechnologies: to remake nature: "*La révolution dans notre conception de la vie qu'a introduite la biologie moléculaire fait de l'organisation vivante le modèle par excellence d'une « nanotechnologie naturelle » qui fonctionne admirablement bien. Qu'est-ce qu'une cellule dans cette vision des choses sinon une nano-usine faite de nanomachines moléculaires capables d'auto-réplication, voire d'auto-complexification ? Les propriétés d'auto-assemblage des virus ou de l'ADN ; le rôle que jouent dans le métabolisme cellulaire des molécules fonctionnant comme des engins macroscopiques, ayant les fonctions qui d'une roue, qui d'un fil, qui d'un interrupteur, le tout fonctionnant au moyen de « moteurs » alimentés par énergie chimique, optique ou électrique ; les connexions qui se réalisent spontanément entre les molécules du système nerveux pour traiter et transmettre l'information : autant d'exemples qui prouvent que la nature, avec le vivant, a « su créer » de l'organisation. Puisque la nature n'est pas un sujet, le terme technique que l'on utilise pour décrire ce prodige est celui d'auto-organisation*" (p. 411).
24. M. FABRE-MAGNAN, introduction to C. LABRUSSE-RIOU, *Ecrits de bioéthique*, cit., p 7.
25. E. DREXLER, CH. PETERSON, G. PERGAMIT, *Unbounding the Future: the Nanotechnology Revolution*, New York, 1991. See M. C. ROCO, W.S. Bainbridge (eds.), *Societal implications of nanoscience and nanotechnology*, Kluwer, Dordrecht, 2001. Here M.C. ROCO affirmed that "*a revolution is occurring in science and technology*" (p. 1). In this case nanotechnology is considered to be a technological novelty.
26. To define the relationship between man, technology and technique, and to warn man from a reductionist drift, Prof. S. COTTA had defined the technique as "*una mentalità, un modo di essere e pensare prima ancora di produrre o fabbricare. E' una mentalità che guarda alle cose sotto il profile esclusivo del discontinuo, che permette di scomporle e ricomporle, come nota Bergson; secondo il criterio dominante dell'utilizzabilità e del calcolo, per dirla con Heidegger, e quindi della manipolazione utilitaria"* (S. COTTA, *L'uomo tolemaico*, Milan, Rizzoli, 1975, p. 45) and the same report as "*interazione propulsiva*" (p. 49). In an earlier book (*La sfida tecnologica*, Il Mulino, Bologna, 1968), the philosopher of law called "*technological energy*" the link among science, technique and production, wrote about their "*progressive interaction*" and stressed that human needs activate this connection. In this way, the collaboration between man and machine becomes an integration (cf. p. 39)
27. For the economic and social significance of the invention of the steam engine see C. ONION, *Men, technology, economics*, Milano, 1977. Also relevant is the volume of P. MANTOUX, *La révolution industrielle au XVIII^e siècle. Essai sur les commencements de la grande industrie moderne en Angleterre*, Paris, 1959. The A. presents a historical overview of technique and technology.
28. B. SAINT SERNIN stresses that "*Aux XVIII^e et XIX^e siècles, le mot 'technology' veut dire, conformément à son étymologie (technôn logos), la science des techniques: leur histoire, leur évolution, leur classification, leur interactions, etc. On s'emploie, par example, à constituer une science des machines. A partir du milieu du XIX^e siècle, l'étude du rendement des machines à vapeur, puis la fabrication des colorants prennent un tour imprégnées scientifique des techniques de savoir scientifique et apparaissent, vers le début du XX^e siècle, en anglais, on se met à désigner par le terme de technologies les techniques dont la racine est en partie scientifique. En 1917, le mot 'biotechnology', nous l'avons vu, apparaît aux Etats-Unis. Dans la seconde moitié du XX^e siècle, les industries à base if développent scientifique et le terme de 'technology' en vient à se substituer à celui de 'technique', désigner pour les processus et les produits dont la mise au point des savoirs scientifiques incorpore. Toutefois, il est exceptionnel que les 'technologies' compréhensibles soient de part en part à l'aide des sciences, le plus souvent, elles comportent un mélange de processus qui sont explicables scientifiquement et de processus qui ne le sont pas. La technologie a deux objets : la production des biens de l'organization de la production et des échanges. Depuis les années 1920, l'économie mathématique a développé des méthodes (programmation mathématique, méthode PERT, etc.) Qui permettent d'optimiser l'organization de la production et des échanges. Ces deux sortes de technologies if conjuguent dans les entreprises et les Etats modernes"* (*Le rationalisme qui vient*, Paris, p. 324). See also A. E. MUSSON, E. ROBINSON, *Science and Technology in the Industrial Revolution*, Bologna, 1970.
29. See G. O. LONGO, "Lo scenario: uomo, tecnologia e conoscenza", in G. M. APUZZO, S. ARNALDO, E. BARBIERI MASINI (eds.), *Uomo, tecnologia e territorio*, Consorzio per l'AREA di ricerca scientifica e tecnologica di Trieste, Trieste, 2003, pp. 20-44.
30. See J. LE GOFF, *Il corpo nel Medioevo*, in CATALDI VILLARI F. (tr.) Laterza, Bari-Rome, 2005.

From a Darwinian and Lamarkian perspective, man is drawn, moved, and extended by technology. A closer connection with technological instruments can produce the man's loss of control over himself (his data, for example). All this largely argues traditional paradigms of corporeality, identity, and personality. And the law, that is oriented toward regulating technologies, knows them on the basis of its traditional categories[31]. On the one side this process attempts to update and remodel law, while on the other hand it solves the "obsolescence" of certain legal instruments with a strong doctrinal and jurisprudential creativity[32].

With nanotechnologies, questions of regulation return with force, and have implications for bioethics. The realm of nano-technoscience is dense, and ethical perspectives vary considerably in this field. However, commentators and researchers share a concern about a specific worrisome issue: the lack of appropriate ethical and legal principles and processes (associated with issues including health risks, human body manipulation, and private life violation), to guide nanotechnological R&D, commercialization, and final use. Some authors partially reject this concern by suggesting that Nanoscience and Nanotechnologies do not constitute an autonomous category, and that they are instead just the operative result of other traditional areas of study. Nonetheless, the nanotechnological debate brings up the semantic and content issues of bioethics and foments a contentious discussion emphasizing human dignity. Issues include enhancement *versus* therapeutic intervention, traceability *versus* privacy, and societal benefits *versus* risks.

Given the above arguments about the difficulties of articulating a common vision of nanotechnology, it is hard to create uniform and shared ethical and legal solutions. However, we can trace applicable tools of bioethics and the law that have bearing on potential regulation of nanotechnology. By doing so we intend to clarify that, although we still lack a specific structure for ethical and legal solutions in this area, law and (bio)ethics of technologies[33] already possess some elements that can come to our aid.

We have already mentioned the "posture of the law". Now we have to make a brief digression into bioethics. This is intended (under a "communicational" point of view, *à la* J. HABERMAS) as a framework to discuss the applicability of traditional principles such as human dignity to the nanotechnological debate. We find that the application of the principle of human dignity is possible thanks to the circulation of its "normative model".

We note that according to the Encyclopedia of Bioethics, the discipline is basically the "*systematic study of human conduct in the life sciences, given and examined in the light of the principles and ethical values or even better, moral values*." This can be considered to be a static definition of bioethics.

According to the Universal Declaration on Bioethics and Human Rights, the term bioethics "*refers to the systematic, pluralistic and interdisciplinary and to the resolution of ethical issues raised by medicine, life sciences and social sciences as applied to human beings and their relationship with the biosphere, including issues concerning the availability and accessibility of scientific and technological developments and their applications*".

We lack room for a full discussion of this issue, but stress that we share the view expressed by C. BYK on bioethics. In one of his many articles[34], Judge Byk proposed a "dynamic definition of bioethics", that could become a forum for discussion of the issues raised by the development of biotechnology. Additionally, he called for this dynamic definition to emphasize the inevitable link between culture and bioethics, which connects bioethics to the ambiguities that are often reflected in social debates about the role of technoscience. Applying shared, parallel, unique universal rights to bioethics appears an impossible task if we mainly consider the trans-disciplinary connotation of technoscience. Briefly, there doesn't seem to be a different outcome for "bioethics of nanotechnology".

Scientists fear that individuals will have typical misunderstandings about new technologies that they are not familiar with, leading to reactionary fear and

31. To paraphrase G. DEL VECCHIO (see his book *La giustizia*, published in 1923), we consider that science and law have a common basis – the human dimension, and both use a deontological approach. However they are undeniably different. They use different categories to know reality and are equipped with different logical structures. Thus, it would be dangerous for them to try to absorb each other their characteristics.
32. M.-A. HERMITTE, "Le droit est un autre monde", in *Les objets de droit*, Enquête n. 7, 1999, pp. 17-37.
33. We paraphrase M.-A. HERMITTE, *Les acteurs du processus de décision*, document available from http://lodel.ehess.fr/cenj/docannexe.php?id=168.
34. C. BYK, "La bioéthique mondiale et la culture", in *Journal International de Bioéthique*, 2005/1-2 - Volume 16, pp. 11-12.

criticism. However in order to adequately govern nanotechnological developments we need a process of discussion and collaboration between scientists, experts, and policy makers, who must also listen to the general public. As a global phenomenon, bioethics is inevitably mixed with culture, and influenced by cultural peculiarities and diversity; technoscience has a "social dynamic" aspect. Thus, in order to discuss bioethics we must acknowledge its cultural roots. This includes, for example, explaining why certain principles of bioethics are embedded at the constitutional level in some countries and not in others. These country-specific differences are linked to varying balances of power and roles within the political systems. Another factor is citizen participation. For example, in France, progressive forces have demanded attention from policy makers and legislators, which has influenced the role of bioethical principles.

The turmoil associated with bioethical decision-making explains why we do not need a nano-bioethics that mixes with apocalyptic nightmares and utopian hopes[35]. Even if the historical and theoretical development of nanotechnologies in the '80 was set up as a fable, and although the matter received ambivalence of the civil society[36], we agree with A. RIP that bioethical implications of nanotechnologies and nanosciences are almost linked to the "*NEST (New and Emerging Science and Technology) ethics*"[37].

In short, it's good to note that even in the complex case of nanotechnology, there are ethical issues to which ethical principles can be applied. Some examples of this include the protection of human dignity, the promotion of human integrity, the principle of providing care, the protection of public health, and the respect for the principles of proportionality, precaution and responsibility. These principles should be applied to anything that the European Commission identifies as "*science and the new and emerging technologies*"[38].

As previously considered, no meta-bioethics is valid for all cultures, nor nanobioethics exists or is required by operators. Moreover, at present time there is no national, EU or transnational legislation[39] specific to nanotechnologies or nanomedicine.

The European Union's recent experience has called attention to the scientific, political, ethical and legal issues that are typical to the different disciplines that contribute to nanotechnology[40].

35. B. GORDJIN, "Nanoethics: From Utopian Dreams and Apocalyptic Nightmares towards a more Balanced View", in *Science and Engineering Ethics*, vol.11, n. 4, 06/2005.

36. The public is paradoxically indifferent to new "micro" technology. People interact with it and use it like any other instrument or object. Indeed, the public approves the advancement of technology to the extent that it will improve the human body according to the fundamental rule of good life. However, the public expresses concerns of loss of human qualities resulting from the "technologization" of man. Consider for example the confusion caused by the use of the word "nanotechnology" As already seen, the fear is often fueled by a confused or nonexistent social debate, as well as by the fear that artificial victories are detrimental to nature.

37. A. RIP, "Nano-ethics as NEST-ethics: Patterns of Moral Argumentation about New and Emerging Science and Technology", in *Nanoethics*, 2007, vol. 1, p. 4.

38. In England in 1985, A. JEFFREYS made a paternity test for the purposes of an immigration case. The case was advanced by DNA analysis. See A. J. JEFFREYS, V. WILSON, S.L. THEIN, "Individuals specific fingerprints of human DNA", *Nature*, 1985, n. 316, pp. 76-79. For further insight on the traditional theme of the Human Genome Project in terms of legal policy, we suggest the excellent essay by M.-A. HERMITTE, "Le séquençage du génome humain: liberté de recherche et démarche démocratique", in *RIDE*, 1993 n. 1, p. 29. Since this essay there have been several studies and applications regarding genetics. Now there are different horizons for the nano-size subjects. See for example the discussion of the Comité consultatif national d'éthique pour les sciences de la vie et de la santé (*Questions posées par les nanosciences, les nanotechnologies et la santé*, Report n. 96) about the medical applications of nanoscience: "*La réalisation en routine clinique de la carte génétique (puces à ADN et « lab on chips », et l'identification d'un grand nombre de susceptibilités génétiques de l'individu par des outils diagnostiques et des techniques analytiques ; Implantation chez un patient de biosenseurs multi-paramétriques, de matériel bioactif à usage local ; Mise en oeuvre de marqueurs fonctionnels pour une imagerie non invasive, d'agents assurant l'identification de la cible à traiter et portant un dispositif thérapeutique dans le domaine de la nano-imagerie statique et interventionnelle à l'échelle moléculaire, subcellulaire et cellulaire : « théranostics »*" (p. 5). For a U.S. perspective on human genetics and applications in the field of tissue samples and biobanks see the interesting recent paper, R. HARDCASTLE, *Law and the Human body. Property Rights, Ownership and Control*, Hart Publishing, Oxford / Portland, 2007. Despite the technical content, the volume is easy to read. Starting from the consideration of the human body, the Author takes into consideration the rights concerning it and stresses their proprietary / non-proprietary nature.

39. See the recent K. W. ABBOTT, S. GOPALAN, G. MARCHANT, D. SYLVESTER, "Models for the international regulation of nanotechnology", Paper presented at the meeting of the Association of International Studies, San Diego, California, USA, 03.22th.2006 (available on the Internet http://www. allacademic.com/meta/p98931_index.html).

40. As an example, consider EGE, Ethical aspects of ICT implants in the human body. Opinion to the Commission by the European Group on Bioethics, Brussels, 17.03.2008, http://ec.europa.eu/european_group_ethics/avis/index_en.htm, ETP Nanomedicine. Nanotechnology for Health, Strategic Research Agenda for Nanomedicine, European Technology Platform Nanomedicine, November 2006, http://cordis.europa.eu/nanotechnology/nanomedicine.htm; European Commission, Cooperation program objectives. Includes Health, Nanoscience, Nanotechnologies, Materials and Production Technology, and other thematic programs, 2006; http://cordis.europa.eu/fp7/cooperation/home_en.html European Commission for Nanosciences and Nanotechnology, *A Plan Action for Europe 2005-2009*. COM (2005) 243fin, European Commission, Brussels, 07.07.2007; http://cordis.europa.eu/nanotechnology/actionplan.htm; European Parliament, *Resolution on nanosciences and nanotechnologies: an action plan for Europe*, Strasbourg, 24.06.2007, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT% 2BTA% 2BP6-TA-2006-0392% 2B0% 2BDOC% 2BXML% 2BV0 / /.

The most interesting question regarding our look at what "exists" relates to the capacity of the existing general principles to adapt to the regulatory issues posed by nanometric products.

The questions are usually posed as follows:

1. Are rules adequate to cope with the risk assessment of products, chemicals, food (health / environmental risks and toxicological implications)?
2. Will there be no further discussion of, or, worse, a reduction of, the international and constitutional protection of human dignity?

If the principle of the American idea was to have an international convention framing the field of nanotechnology as a whole[41], such an aspiration was betrayed at the level of the EU. Instead of reaching international consensus, the European Commission has calmly opted for a strategy of co-regulation and self-regulation that prefers negotiation and mediation and the use of the existing legal and regulatory environment rather than trying a new heterogeneous legislative solution.

The adaptation of existing guidelines, therefore, remains the priority of the Community. This legislative (and cultural) vault has inevitably affected how principles of bioethics and law are worded and applied, including the use of the concept of human dignity.

4. NANOTECHNOLOGY FROM THE PERSPECTIVE OF HUMAN DIGNITY, THE PRINCIPLE OF BIOETHICS AND THE LEGAL MODEL

As we have mentioned, the debates on bioethics focus on acceptability (which became legal in biolaw[42]). We wonder how far to push the research, but we also need to ask ourselves about what criteria we should use to examine the compatibility between scientific and technological progress and the protection of human dignity and the integrity of life.

Such questions require us to define dignity clearly and precisely.

C. LABRUSSE-RIOU has stated that the validity of the principle of human dignity is challenged by "*the issue of borders of the person from the duty to respect their dignity [...] a difficult question because the human being is inseparable from the living – there is no person without biological life – and because in any case, a person may be reduced to living*"[43]. As an example of how human dignity may incur weakness when being contextualized or postponed at the discretion of a court, the author points to the surveys done by M. Th. MEULDERS KLEIN on the topic of human dignity[44]. She argues, in fact, that a determined and unambiguous concept of dignity is impossible due to the four eminent human factors: progress and power, profit, desire and the free pursuit of happiness, and that of usefulness. R. MACKLIN also acknowledged the difficulties of this concept[45] and used the topic of the substitutability of the principle of dignity to support her idea (for example, the respect for individuals, the principle of confidentiality, the right to give and get informed consent).

So far we have demonstrated the difficulties associated with the theoretical principle of dignity[46]: first, that it is a knock-out argument that adds nothing to facilitate the advancement of the discipline and second that it does not facilitate the process by which we determine the extent to which human dignity should be protected and by whom. Third, it is claimed that the principle gives rise to dogmatists who could use it in too deep, and almost an abusive manner.

This last point often emerged during the debate Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on

41. J. DAVIES, *Managing the Effects of Nanotechnology*. Washington: Woodrow Wilson Center's Project on Emerging Nanotechnologies, 2006 (http://www.wilsoncenter.org/index.cfm?fuseaction=news.item&news_id=165552).
42. See C. BYK, *Progrès scientifique et droits de l'homme : la rupture ?,* Available on internet http://www.iales.org/doc_francais/Progres%20scientifique%20et%20droits%20de%20l'homme,%20la%20rupture.pdf
43. C. LABRUSSE-RIOU, *Ecrits de bioéthique*, cit. 322.
44. *Ibidem*, p. 307. See M.TH. MEULDERS KLEIN ''La production des normes en matière de bioéthique'' in CL. NEIRINCK (dir), ''De la bioéthique au biodroit'', in *LGDJ*, Paris, 1994, p.28 e ss.
45. See R. MACKLIN, "Dignity is a useless concept", in *British Medical Journal,* 2003.
46. For discussion of the role of the human dignity in bioethics and biolaw, as well as dilemmas posed in this field by biomedical practice, see R. ANDORNO, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics" in *Journal of Medicine and Philosophy*, n. 0, 2009, pp. 1-18.

Human Rights and Biomedicine. It was stressed that the "*Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine*"[47].

On the contrary, we stand in agreement with the view taken by C. BYK and other distinguished authors[48] that the idea of human dignity has become a key concept in international and national law. In this way, by referring to the national legislation to further specify the broad principle, the legislator has pursued a twofold purpose: first, elevating the principle of human dignity as inherent to the human person and, thereby, indispensable; second, postponing what we would dare call the "dynamic" of a national take-over of the principle in question.

In the case of the EU, the principle of dignity as a principle of value and a principle of law, applies also to nanobiomedicine.[49]

It should be remembered that this approach fully meets the regulatory requirements standing at a supranational "programmatic" level (think here of examples ranging from the Universal Declaration of Human Rights of 1948, to the Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO's General Conference in 1997 and subsequently endorsed by the United Nations General Assembly in 1998, and also think of the UNESCO Universal Declaration on Bioethics and Human Rights, adopted on 19 October 2005). The European Union went in at least two different directions on this topic:

1. One direction was having a founding nature. Thus, human dignity has influenced the most relevant principles contained in the Charter of Fundamental Rights of the Rights of the European Union (2000/C 364/01)[50]. The latter, in fact, has provided some limits to guarantee the interests of the primary system, which cannot be crossed, either by the government or by private parties. Human dignity is certainly the most incisive and penetrating among the principles considered; it is enshrined in art. Human dignity, stated in that provision, is inviolable;

2. The other direction takes into account the criteria for soft law and self-regulation. The European Group of Ethics (EGE) presented its opinion on nanomedicine to President Barroso on 24 January 2007.[51] The introduction to this presentation highlighted that "*all areas of science and new technology developed within the European Union must be consistent with the ethical principles stated in the European Charter of Fundamental Rights. The overall principle of human dignity is spelled out in several chapters of the Charter, both as protective or negative rights (rights not to be unjustly hindered in actions, be it on the individual or he institutional level; and rights to be protected against maltreatment or unjustified risks caused by the actions of others) and as positive rights (rights to be upheld in people's everyday lives and/or raising the standard of living for those who do not have the means to fully participate in the activities of European society)"*. Far from being vague, the EGE engages the principle of dignity with traditional ideas of integrity, autonomy, personal privacy, and also uses risk assessment, to conclude that the principle of dignity is particularly relevant where "*the enabling character of nanotechnology generates familiar biomedical ethics like the gap between*

47. For related information, see Council of Europe – Steering Committee for bioethics, Convention on Human Rights and Biomedicine. Explanatory Report, Strasbourg, 1997. In particular, cf. art. 21.
48. C . BYK, *Progrès scientifique et droits de l'homme : la rupture?*, cit. See also R. ANDORNO, "Dignity of the person in the light of international biomedical law", in *Medicina e Morale*, 2005, n. 1, pp. 91-105.
49. The dignity principle has gradually penetrated the fabric of many European regulatory systems, and has reached outside Europe as well (see, eg., art. 7 of the Swiss Constitution of 18 April 1999: "The dignity of the person should be respected and protected"; article 1, paragraph 2 of the Constitution of Finland 11 June 1999: "*The constitution shall guarantee the inviolability of human dignity and the freedom and rights of the individual and promote justice in society*"; art. 21, par. 1, of the Russian Constitution of 12 December 1993, art. 21, paragraph 1: "*The dignity of the person shall be protected by the state*" . The number of law and normative texts taking into consideration the human dignity can be considered as an index the growing importance of this model. A similar spreading process is also emerging in field of case law and doctrine.
50. See Article 1: "*Human dignity is inviolable. It must be respected and protected*". The mention of the value of dignity is also found in the Preamble of the Charter. For a general overview of this text and the role that the dignity principle played therein, see cf. notations of F. BENOÎT-ROHMER, "La Charte des droits fondamentaux de l'Union européenne", Actes of the Congress, Strasbourg, 06.16th-17th.2000), in *Revue universelle des droits de l'Homme* (Kehl / Strasbourg), vol. 12, No. 1-2, 09/2000.
51. EGE, *Opinion on the ethical aspects of nanomedicine*, n. 21 (http://ec.europa.eu/ european_group_ethics/activities/docs/opinion_21_nano_en.pdf).

diagnostics and therapy or sensitivity of genetic information. This means we build on a familiar pool of ethical and social discussions, from principles of human dignity to generic questions of science ethics". However, the defining inconsistency and increasing[52] regulatory processes have not exempted the Commission[53] from reflecting on the bioethical issues that nanotechnologies present[54]. The European Commission has adopted a Code of Conduct for responsible research in relatively new fields of nanosciences and nanotechnologies (N&N). The Code is voluntary and lists seven general principles on which the Member States are encouraged to initiate actions to ensure the safe development of nanotechnology. At p. 3, the code stresses initiating concrete actions to ensure the safe development of nanotechnology. Also at p. 3, the code stresses that "*nanotechnology, like many other domains, raises issues about protection of fundamental rights. These rights are rooted in the principle of human dignity and shed light on core European values, such as integrity, autonomy, privacy, equity, fairness, pluralism and solidarity*"[55]. This specification allows the Commission to ask that, at national level, high standards of protection of fundamental rights be established and met. Furthermore, it simultaneously calls for the use of the aforementioned precautionary approach.

Of course, we argue that the mechanisms of self-discipline and its effectiveness reflect a legal construct.[56]

The EU has moved upstream to place the bioethical principle of human dignity within the realm of law. Meanwhile, it has moved downstream on the topic of nanotechnology and nanomedicine, to invoke the validity of soft law in the legal systems. This highlights, importantly, how the EU's political terrain attempts a mediation between the development of a market of nanotechnology and, before that, the funding of that research, with the applicability of a recognized system of safeguards, and the application of the precautionary principle.

As for the United States, the relationship between bioethics and human dignity was recently brought back into vogue thanks to the 2008 report "Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics"[57]. Unfortunately, this report only mentioned nanotechnology twice[58]. To some extent it seems that the NNI intends to deal fairly with regard to this porous principle. However, we need to consider how difficult it is to apply the principle of dignity outside of a context where it is legally recognized. This poses problems in relation to the speed of technological innovation and its movement in a globalized economy. However, "*human rights are not lost in any transition to the post human. Their reasons, to the defence of life and dignity, receive a further and even stronger confirmation*"[59].

In conclusion, this survey of the debated topic of nanotechnology has highlighted how the concept of dignity, understood in the (bio)ethical and regulative senses, constitutes a fragile and compromising path. Furthermore, this concept may safeguard the primacy of the human person even at times when technologies could actually be beneficial, rather than damaging. To take this path with balance and moderation can be an arduous undertaking, but fruitful all the same. ■

52. Cf. DUPUY J.-P., GRINBAUM A.: "Living with uncertainty: From the precautionary principle to the methodology of ongoing normative assessment", in *Comptes Rendus Geosciences*, vol. 337, n. 4, 03/2005.
53. This is the maximization of the use of existing regulatory structures. The prevailing method of adaptation, therefore, is creative. With regard to the European Commission, see *Nanotechnologies: A Preliminary Risk Analysis on the Basis of a Workshop organized in Brussels by Health and Consumer Protection Directorate General f the European Commission* (01-02.03.2004), Part 1 (Workshop Outlines), pp. 22-24.
54. Cf. Ch. PHOENIX, E. DREXLER., "Safe exponential manufacturing", in *Nature*, 2004, n. 15, 869-872.
55. See also UNESCO, OECD, the STS Forum, ISO, etc. and in particular the *International Dialogue on Responsible Nanotechnology* (http://cordis.europa.eu/nanotechnology/src/intldialogue.htm).
56. See G. ALPA, "Autotutela e codici di condotta", in *Sociologia del diritto*, 1995, p. 127 et seq.
57. The President's Council on Bioethics, *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics*, Washington, DC, March 2008. Note, that in 2002 a similar report was prepared in which discussion of human cloning included the principle of dignity.
58. Refers to E. PELLEGRINO in his contribution *The Lived Experience of Human Dignity*, p. 514 et seq.
59. S. RODOTÀ, *La vita e le regole. Tra diritto e non diritto*, Feltrinelli, Milan, 2006, p. 87.